



THE GUIDANCE DOCUMENT FOR
THE FBI QUALITY ASSURANCE STANDARDS
FOR FORENSIC DNA TESTING
AND DNA DATABASING LABORATORIES
EFFECTIVE 07/01/2020

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INTRODUCTION

The DNA Identification Act of 1994 required the formation of a panel of distinguished professionals, from the public and private sectors, to address issues relevant to forensic DNA applications. This panel, known as the Federal DNA Advisory Board (DAB), first convened in 1995. The mission of the DAB was to develop and implement quality assurance standards for use by forensic DNA testing laboratories. The scope was quickly expanded to include forensic DNA databasing laboratories as well. The DAB fulfilled its statutory responsibilities, recommending separate documents detailing quality assurance standards for both forensic and databasing applications. The "Quality Assurance Standards for Forensic DNA Testing Laboratories" and the "Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories" were issued by the Director of the Federal Bureau of Investigation in October 1998 and April 1999, respectively.

The "Quality Assurance Standards for Forensic DNA Testing Laboratories" and the retitled "Quality Assurance Standards for DNA Databasing Laboratories" have become benchmarks for assessing the quality practices and performances of DNA laboratories throughout the country. When the Federal DNA Advisory Board's statutory term expired, it transferred responsibility for recommending revisions of these quality assurance standards to the Scientific Working Group on DNA Analysis Methods (SWGDM).

The DNA Identification Act of 1994 also required that the FBI Laboratory ensure that all DNA laboratories that receive federal grant funds or participate in the National DNA Index System (NDIS) demonstrate compliance with the FBI's Quality Assurance Standards (QAS). A laboratory's documentation of compliance with the QAS is measured through an accreditation/audit process. Such accreditation inspections or audits are performed by forensic scientists, either internal or external to the laboratory, and are intended to evaluate and document compliance with established standards.

Since the issuance of the original QAS, the FBI Laboratory recognized that a uniform interpretation guide would minimize interpretation variability among auditors. For the initial QAS, the FBI Laboratory developed, in collaboration with inspection and accreditation agencies and other interested stakeholders, audit documents for assessing compliance with the required Forensic and Databasing standards. Previous Audit Documents contained a checklist for assessing compliance with each standard and additional discussion sections with interpretation guidance for laboratories and auditors.

With the 2020 QAS revisions, the QAS discussion sections for the Forensic and Databasing Standards, formerly part of the Audit Documents, have been transitioned into this QAS Guidance Document. This Guidance Document clarifies standards, as needed, and provides additional guidance to assist the laboratory and auditors in determining compliance. The Forensic and Databasing Audit Documents now contain only the checklists for assessing compliance with each standard.

The revised discussions in this QAS Guidance Document are applicable to the Forensic and Databasing QAS which will take effect July 1, 2020 and are not to be applied retroactively. The Forensic and Databasing QAS are the primary resources for the definitions and quality assurance standards and take precedence over this Guidance Document which should be consulted only for additional clarification as a secondary resource.

Standard 1. Scope and Applicability

| Forensic Standard 1 | Database Standard 1 |
|-----------------------------|---------------------|
| No additional guidance | |
| Latest Revision: 07/01/2020 | |

Standard 2. Definitions

| Forensic Standard 2 | Database Standard 2 |
|--|---------------------|
| <p>Refer to the definitions in the QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES or QUALITY ASSURANCE STANDARDS FOR DNA DATABASING LABORATORIES effective July 1, 2020.</p> <p>Throughout this document “CODIS Administrator” is used to refer to the casework CODIS Administrator or CODIS Administrator, as applicable to the particular standard.</p> | |
| Latest Revision: 07/01/2020 | |

Standard 3. Quality Assurance Program

| Forensic Standard 3.1 | Database Standard 3.1 |
|---|-----------------------|
| <p>To successfully satisfy Standard 3.1, compliance must be demonstrated with all of the substandards of Standard 3.1.1 and Standard 3.1.2.</p> <p>The quality system must be appropriate to the testing activities performed by the laboratory. Various approaches may be used to accomplish the quality system, as long as the requirements are clearly defined in a quality assurance program. A laboratory may choose the format in which it maintains its quality system, as long as it is on-site and readily available to DNA personnel.</p> <p>A laboratory’s quality system must be equivalent to or more stringent than the “Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories” or “Quality Assurance Standards (QAS) for DNA Databasing Laboratories”, as applicable. If a laboratory has requirements more stringent than the QAS, it must be audited to the more stringent requirements. For example, if the laboratory is in compliance with these standards, but is not adhering to its own more stringent requirements, the finding shall be documented in the Audit Document checklist.</p> | |
| Latest Revision: 07/01/2020 | |

| Forensic Standard 3.1.1 | Database Standard 3.1.1 |
|-------------------------|-------------------------|
|-------------------------|-------------------------|

Standards 3.1.1.1 through 3.1.1.15 are elements of the quality system that a laboratory must ensure are documented or referenced in a quality system manual(s). The laboratory may rely on laboratory or agency-wide policies, procedures, and guidelines that address such elements, but must ensure that the laboratory references them. The following are the elements as defined by **Standards 3.1.1.1 through 3.1.1.15** and what should be addressed within each of those elements. Further requirements for each element will be found within the corresponding standard.

- **Goals and objectives** must define, establish, or reference the goals and objectives for the laboratory.
- **Organization and management** must define, establish, or reference the organization and management structure of the laboratory, the interrelationship of the various DNA positions, as well as the responsibilities of personnel. (Refer to **Standard 4**)
- **Personnel** must define, establish, or reference the educational and experience requirements for each technical position within the laboratory. (Refer to **Standard 5**)
- **Training** must define, establish, or reference the training requirements for qualifying personnel to perform analytical procedures on forensic, database, known and/or casework reference samples. (Refer to **Standard 6**)
- **Facilities and evidence control** must define, establish, or reference the laboratory's procedures for laboratory security and its approach for maintaining the integrity of DNA analyses and evidence examination as well as the procedures for handling and preserving evidence and the laboratory's definitions for what constitutes work product and evidence. (Refer to **Forensic Standard 7**)
- **Facilities and sample control** must define, establish, or reference the laboratory's procedures for laboratory security and its approach for maintaining the integrity of DNA analyses as well as the procedures for handling and preserving database, known and/or casework reference samples and the laboratory's definitions for what constitutes work product and evidence. (Refer to **Database Standard 7**)
- **Validation** must define, establish, or reference the practices and procedures for evaluating and implementing new methods used by the laboratory. (Refer to **Standard 8**)
- **Analytical procedures** must define, establish, or reference the use of current and approved procedures for validated methods. (Refer to **Standard 9**)

- **Equipment** must define, establish, or reference the laboratory’s program for maintaining equipment and conducting performance checks of equipment and instruments. (Refer to **Standard 10**)
- **Reports** must define, establish, or reference the laboratory’s procedure for how it maintains case files, generates laboratory reports, and maintains confidentiality and privacy of reports, case files, and DNA records and databases. (Refer to **Forensic Standard 11**)
- **Documentation** must define, establish, or reference written procedures for taking and maintaining records and documentation for database, known or casework reference samples, and its policy for describing how the laboratory maintains confidentiality and privacy when applicable to reports, files, and DNA records and databases. (Refer to **Database Standard 11**)
- **Review** must define, establish, or reference how the laboratory performs its technical and administrative review of all case files or databasing DNA records, the qualifications of personnel who perform reviews, and the review procedures associated with the upload of DNA data. (Refer to **Standard 12**)
- **Proficiency testing** must define, establish, or reference the laboratory’s program for administering external proficiency tests to DNA personnel and evaluating the results of those proficiency tests. (Refer to **Standard 13**)
- **Corrective action** must define, establish, or reference the laboratory’s process for addressing nonconformities in casework or database analysis, proficiency testing, testimony, and audits. (Refer to **Standard 14**)
- **Audits** must define, establish, or reference the laboratory’s program for participation in internal and external audits to the Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories or DNA Databasing Laboratories. (Refer to **Standard 15**)
- **Professional Development** must define, establish, or reference the laboratory’s program for continuing education and annual review of analyst testimony. (Refer to **Standard 16**)
- **Outsourcing ownership** must define, establish, or reference the laboratory’s procedures for outsourcing samples and accepting ownership of the products of DNA analyses. Laboratories shall address this element, regardless of whether or not the laboratory outsources. For example, outsourcing may be referenced in the quality manual as “Not Applicable” or “NA” if the laboratory does not outsource any analyses. (Refer to **Standard 17**)

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Forensic Standard 3.1.2

Database Standard 3.1.2

Any document referenced within the quality manual(s) must be available on-site or readily accessible (e.g., available online).

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Forensic Standard 3.2

Database Standard 3.2

To successfully satisfy **Standard 3.2**, compliance must be demonstrated with all of the components of **Standard 3.2**.

The laboratory may address document retention through a single policy or a combination of several policies. However, retention of each of the listed documents must be addressed.

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Forensic Standard 3.3

Database Standard 3.3

An annual review (calendar year) of the quality system is important for ensuring that measures are being taken by the laboratory to continually provide the highest quality of service. The annual review may identify areas in need of attention and provide the basis for changes to the quality system. Quality system documents that are updated or revised in the calendar year may be exempt from an additional annual review, provided that the technical leader's approval of the quality system review addresses these revisions. The annual review of the quality system must be independent of the audit requirement as stated in **Standard 15**.

The laboratory must demonstrate that the annual review of its quality system is performed under the direction of the technical leader and the completion of the review must be documented and approved by the technical leader.

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Forensic Standard 3.4

An annual review of case files is a useful quality assurance mechanism to evaluate the products of forensic DNA analysis.

A case file review must be conducted each calendar year. The scope of the review must be defined and approved by the technical leader and address both the representative sample and the time period of the case files under review. For example, the time period may include case files from the previous calendar year or for a specified period of time.

The technical leader will determine what will be used as the representative sample for the annual review, and the representative sample may vary from year to year. The technical leader may select the sampling based on corrective actions, perceived analytical gaps, and/or at random. The sampling may be based on a percentage or a specified number of cases. Additionally, the representative sample may be selected based on the forensic samples tested, technology, conclusions reported, complexity of the typing results, or cases where testimony has occurred and transcripts were

available for review. As examples, a representative sample may be a percentage of all sexual assault cases, a percentage of all YSTR cases, a specific number of random cases from each analyst, or a specific number of complex mixture cases.

This annual review may not be replaced by technical reviews as a part of **Standard 12**.

The annual audit to these standards required by **Standard 15** cannot be used to replace the annual review of case files; however, the annual case file review may be conducted concurrently with an internal audit.

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Database Standard 3.4

An annual review of sample processing records is a useful quality assurance mechanism to evaluate the products of DNA databasing analysis.

A review of sample processing records must be conducted each calendar year. The scope of the review must be defined and approved by the technical leader and address both the representative sample and the time period of the processing records under review. For example, the time period may include processing records from the previous calendar year or for a specified period of time.

The technical leader will determine what will be used as the representative sample for the annual review, and the representative sample may vary from year to year. The technical leader may select the sampling based on corrective actions, perceived analytical gaps, and/or at random. The sampling may be based on a percentage or a specified number of database analyses. Additionally, the representative sample may be selected based on the database samples tested or technology.

This annual review may not be replaced by technical reviews as a part of **Standard 12**.

The annual audit to these standards required by **Standard 15** cannot be used to replace the annual review of sample processing records; however, the annual sample processing records review may be conducted concurrently with an internal audit.

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Standard 4. Organization and Management

Forensic Standard 4.1

Database Standard 4.1

To successfully satisfy **Standard 4.1**, compliance must be demonstrated with all of the substandards of **Standard 4.1**.

For **Standard 4.1.2**, **Standard 5.2.5** and its substandards must be satisfied in order to demonstrate that the technical leader is accountable for the technical operations. **Standard 4.1.2** does not preclude, for example, the existence of additional program or technical leaders, each of whom may be assigned a subset of clearly defined duties (e.g., training program manager, quality assurance program manager, assistant technical leader); however, a single DNA technical leader, as defined in the laboratory's organizational chart, will retain the ultimate DNA-related authority and oversight responsibility for the laboratory's technical operations. However, a laboratory may have more than one technical leader if there is no overlap between them and the role of each is clearly defined. For example, a laboratory may designate a technical leader over a specific technology (e.g., a mitochondrial DNA technical leader and an STR technical leader), over an operational group (e.g., a casework technical leader and a databasing technical leader), or for a multi-laboratory system, technical leaders may be assigned to each location with each having the ultimate authority over the designated technology, operation group or laboratory location, as applicable.

For **Standard 4.1.3**, **Standards 5.3.4** and its substandards, and **Standard 5.3.5** must be satisfied in order to demonstrate that the CODIS administrator is accountable for CODIS operations on-site at each individual laboratory facility using CODIS.

For **Standard 4.1.4**, **Standard 5.4** and its substandards must be satisfied in order to demonstrate that the DNA analysts are full-time employees and are qualified. Contract employees cannot be counted when determining if a laboratory satisfies the two full-time employee requirement of **Standard 4.1.4**.

For **Standard 4.1.5**, an organizational chart, job descriptions, and/or other laboratory documentation must specify the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis. A current organizational chart can be used to demonstrate the interrelation of personnel. The organizational chart may reference specific personnel by name with their specific position assignments (e.g., technical leader, casework CODIS administrator), or the organizational chart may reference the specific position assignments. If the organizational chart references the specific position assignments, those assignments need to be augmented with the job description for the member of the laboratory assigned to the specific position. (Refer to **Standard 5.1.1**)

For **Standard 4.1.6**, the laboratory must have a documented contingency plan in place, approved by laboratory management, for a vacancy in the technical leader position and in the event the number of qualified analysts falls below two full-time employees who are qualified analysts. This plan may be a single policy or a combination of several policies. A contingency plan should include or address the appropriate notifications naming an individual who may serve in the technical leader position, the time period that individual may serve, and how the laboratory will proceed if no one is qualified. The contingency plan must also address the laboratory's course of action in the event the number of qualified analysts falls below

two full-time employees who are qualified analysts. The contingency plan for a multi-laboratory system in the event the number of qualified analysts falls below two full-time employees who are qualified analysts may include or address the availability of similarly trained analysts that can temporarily be reassigned to fill an analyst vacancy.

For an NDIS participating laboratory, the contingency plan for how the laboratory will proceed if no one is qualified to fill the technical leader vacancy or in the event the number of qualified analysts falls below two full-time employees who are qualified analysts requires the notification of the NDIS Custodian and State CODIS Administrator as required by the *NDIS Operational Procedures Manual*. Refer to Appendix B for the Contingency Plan Notification Form. If a contingency plan was submitted to the FBI, then documentation must be reviewed to ensure that DNA analytical procedures on new casework or new database analyses were not initiated until FBI approval was granted. Casework or database analyses in which DNA analytical procedures have been initiated prior to the technical leader's vacancy may be completed. Casework or database analyses in which DNA analytical procedures have been initiated may not be able to be completed if the number of qualified analysts falls below two full-time employees who are qualified analysts.

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| Forensic Standard 4.2 | Database Standard 4.2 |
|--|------------------------------|
| <p>The laboratory policy must specify the date of hire/appointment/promotion or the date of qualification as the defined date to be used by the laboratory for determining the applicable version of the <i>Quality Assurance Standards for Forensic DNA Testing Laboratories</i> or <i>Quality Assurance Standards for DNA Databasing Laboratories</i> for requirements to assess education, experience and training.</p> | |
| <p>If an individual does not change her/his role with a promotion or appointment (e.g., Analyst I to Analyst II, Alternate CODIS Administrator to CODIS Administrator), then reevaluation of her/his education, experience and training is not required. If an individual does change her/his role with a promotion or appointment (e.g., Analyst to Technical Leader, Technician to Analyst, Analyst to CODIS Administrator), then evaluation of her/his education, experience and training for the new role is required.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

Standard 5. Personnel

| Forensic Standard 5.1 | Database Standard 5.1 |
|--|------------------------------|
| <p>To successfully satisfy Standard 5.1, compliance must be demonstrated with all of the substandards of Standard 5.</p> | |
| <p>Appendix D shall be completed by auditors conducting external QAS audits. Individuals in the positions of technical leader, CODIS administrator, and analyst or</p> | |

technical reviewer will be listed in Appendix D if compliance with **Standard 5.1** and the applicable standards for education, experience, and training are demonstrated. The minimum education, experience and training qualifications of those individuals reviewed and documented in Appendix D in two successive external audits of the laboratory system are considered compliant with **Standard 5.1** and do not require additional review, provided that the individuals are in the same role and Appendix D from the past audit documents are available. However, this in no way prohibits the auditor from performing such additional reviews as that auditor(s) may deem appropriate or necessary. If an individual previously memorialized as an analyst or technical reviewer in Appendix D becomes a technical leader or CODIS administrator, the applicable standards for education, experience, and training must be reviewed for that individual and must be memorialized after two successive external audits with respect to the new position.

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Forensic Standard 5.1.1

Database Standard 5.1.1

Job descriptions must be current and available for all laboratory personnel, accurately defining the technical and/or administrative responsibilities associated with each position. Formal job descriptions may be augmented by administrative or laboratory documents (e.g., personnel records, procedures and manuals) that define the responsibilities, duties, and skills.

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Forensic Standard 5.1.2

Database Standard 5.1.2

Technical personnel include those individuals (however titled) who are involved in testing and support of testing (e.g., make reagents, maintain instruments) of forensic, casework reference, or database samples. Individuals not involved in the stream of testing (e.g., evidence management, sample control, administrative, clerical) are not considered technical personnel.

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Forensic Standard 5.2

Database Standard 5.2

Full-time shall be considered the standard work week as defined by the laboratory or its organizational umbrella. The technical leader must be a full-time employee of the laboratory or laboratory system although not required to occupy physical (on-site) facility space if the technical leader oversees multiple laboratories of a multi-laboratory system.

If the minimum education, experience and training qualifications of the technical leader have been reviewed and documented in the Appendix D of two prior external audit documents of the laboratory system where the technical leader is employed, then **Standards 5.2.1 through 5.2.4** do not require review provided that the Appendix D from the past audit documents are available.

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| Forensic Standards 5.2.1 and 5.2.1.1 | Database Standards 5.2.1 and 5.2.1.1 |
|---|--------------------------------------|
| <p>A biology-, chemistry-, or forensic science-related degree must have science and laboratory-based coursework as an integral component. Criminal justice degrees that do not include science coursework (lectures and lab work) are not considered to be forensic science-related degrees.</p> <p>For technical leaders appointed or hired on or after July 1, 2009, a minimum of four courses (biochemistry, genetics, molecular biology, and statistics or population genetics) totaling at least 12 semester or equivalent credit hours must be completed successfully (college- or university-determined passing grade).</p> <p>The DNA training program previously offered by the FBI Laboratory, with graduate credit hours from the University of Virginia, may be applied toward the molecular biology coursework requirement associated with this standard. Unless specifically stated by the FBI, other FBI courses do not fulfill this requirement.</p> <p>If the technical leader possesses a waiver from ASCLD as per Standard 5.2.1.4, Standards 5.2.1, 5.2.1.1, 5.2.1.2, and 5.2.1.3 are not applicable.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standards 5.2.1.2 and 5.2.1.3 | Database Standard 5.2.1.2 and 5.2.1.3 |
|--|---------------------------------------|
| <p>If coursework consists of the title listed in Standard 5.2.1 (biochemistry, genetics, molecular biology, and statistics or population genetics), the coursework shall be considered to meet the integral component requirement in Standard 5.2.1.2.</p> <p>Coursework is generally assessed as the set number of credits on a transcript. Each course topic must be satisfied by a course in that subject or a course that is considered to meet the integral component requirement in Standard 5.2.1.2.</p> <p>For Standard 5.2.1.3, additional details on coursework to satisfy Standard 5.2.1 are listed below.</p> <p>Absent a course titled "Biochemistry," coursework used to fulfill the biochemistry requirement should include the following integral components:</p> <ul style="list-style-type: none"> • Structure, function, and interaction of biological macromolecules such as proteins, carbohydrates, lipids and nucleic acids • Enzymes and chemistry of enzyme-catalyzed reactions • DNA, RNA, and protein synthesis • Signal transduction • Metabolism • Cell membrane transport <p>Absent a course titled "Genetics," coursework used to fulfill the genetics requirement should include the following integral components:</p> | |

- Laws and patterns of inheritance
- Basic structure and function of genes and chromosomes
- Mutation
- Mitosis/Meiosis
- Recombination
- Gene expression

Absent a course titled “Molecular Biology,” coursework used to fulfill the molecular biology requirement should include the following integral components:

- Prokaryotic and eukaryotic genome structure and function
- Interrelationship of DNA, RNA, and protein synthesis
- Transcription, translation, replication
- Gene expression and regulation
- Recombinant DNA techniques
- PCR
- DNA sequencing

Absent a course titled “Population Genetics,” coursework used to fulfill the population genetics requirement should include the following integral components:

- Estimation and testing of measures of allelic association within and between loci (Hardy-Weinberg principle)
- Description and estimation of measures of relatedness at the individual and population level (population structure)
- Genetic drift, mutation, migration and selection

Absent a course titled “Statistics,” coursework used to fulfill the statistics requirement should include the following integral components:

- Descriptive statistics
- Sampling uncertainty and sampling distributions
- Confidence limits and intervals
- Discrete and continuous variables
- Estimation and hypothesis testing, including the use of likelihoods
- Laws of probability and independence
- Bayes' Theorem

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Forensic Standard 5.2.1.4

Database Standard 5.2.1.4

The ASCLD waiver is permanent and portable. Documentation of the waiver must be available. The application for the ASCLD waiver was available until October 1, 2000 and is no longer available.

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Forensic Standard 5.2.2

Technical leaders appointed or hired prior to July 1, 2009 must have a minimum of three years of forensic DNA experience obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters. This includes criminal justice agencies where forensic research/training and caseworking laboratories are separate entities but reside under the same facility-wide organizational umbrella. It is not necessary for the technical leader to function (or to have functioned) as a qualified analyst if appointed or hired prior to July 1, 2009. Satisfaction of the minimum experience requirements shall only be applicable to the specific laboratory system where the technical leader is employed prior to July 1, 2009 and shall not be portable.

Technical leaders appointed or hired on or after July 1, 2009 must demonstrate compliance with **Forensic Standard 5.2.2** through documented employment as a qualified analyst on forensic samples. Training records, authorization records, or previous Appendix D with the Technical Leader memorialized as an analyst may be used to demonstrate the technical leader was a qualified analyst.

It should be noted that the experience time frame is measured not by the number of years with any particular employer but rather by the number of years in a position specific for gaining the experience necessary to satisfy this standard.

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Database Standard 5.2.2

Technical leaders appointed or hired prior to July 1, 2009 must have a minimum of three years of forensic, databasing or human identification DNA laboratory experience obtained at a laboratory where DNA testing was conducted for identification, databasing or forensic purposes. This includes criminal justice agencies where forensic research/training and databasing or caseworking laboratories are separate entities but reside under the same facility-wide organizational umbrella. It is not necessary for the technical leader to function (or to have functioned) as a qualified analyst if appointed or hired prior to July 1, 2009. Satisfaction of the minimum experience requirements shall only be applicable to the specific laboratory system where the technical leader is employed prior to July 1, 2009 and shall not be portable.

Technical leaders appointed or hired on or after July 1, 2009 must demonstrate compliance with **Database Standard 5.2.2** through documented employment as a qualified analyst on database or forensic samples. Training records, authorization records, or previous Appendix D with the Technical Leader memorialized as an analyst may be used to demonstrate the technical leader was a qualified analyst.

It should be noted that the experience time frame is measured not by the number of years with any particular employer but rather by the number of years in a position specific for gaining the experience necessary to satisfy this standard.

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| Forensic Standard 5.2.3 | Database Standard 5.2.3 |
|--|--------------------------------|
| <p>If a technical leader appointed on or after July 1, 2020 was not a qualified analyst, currently or previously, in each technology for which they will be responsible, the laboratory will ensure that the technical leader has documented training within one year of appointment. Training should be sufficient to understand the scientific theory, evaluate the analysis and interpretation, and conduct troubleshooting as required by the technical leader responsibilities.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 5.2.4 | Database Standard 5.2.4 |
|---|--------------------------------|
| <p>Evidence of successful completion of the FBI DNA Auditor training will be assessed through an FBI-issued certificate. The technical leader shall have successfully completed the FBI's QAS auditor training within one year of assuming the technical leader role or position. If the technical leader has already successfully completed the FBI's QAS auditor training on the FBI Audit document, no additional QAS auditor training shall be required. However, it is strongly recommended that the technical leader complete the FBI's most recent QAS auditor training.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 5.2.5 | Database Standard 5.2.5 |
|--|--------------------------------|
| <p>To successfully satisfy Standard 5.2.5, compliance must be demonstrated with all of the substandards of Standard 5.2.5.</p> | |
| <p>For Standard 5.2.5.1, overseeing the technical operations of the laboratory may include ensuring that technical assistance in matters of analysis, interpretation, instrumentation, and troubleshooting is available to laboratory staff.</p> | |
| <p>For Standard 5.2.5.2, while other laboratory personnel (such as director or quality manager) may also have the authority to suspend technical operations for the laboratory or an individual, the authorization of the technical leader is required to initiate or resume the technical operations for the laboratory or an individual.</p> | |
| <p>For Standard 5.2.5.4, if an analyst or technical reviewer has coursework with titles other than those listed in Standard 5.4.1, the technical leader is responsible for reviewing the syllabus, letter from the instructor, or other documentation to ensure the integral component (refer to Standard 5.2.1.3) for that course was met.</p> | |
| <p>For Standard 5.2.5.5, a laboratory that does not currently outsource must still demonstrate that the technical leader has this responsibility.</p> | |
| <p>For Standard 5.2.5.9, it is the responsibility of the contract employee to disclose employment by multiple NDIS participating laboratories and/or vendor laboratories to all employing laboratories for which the contract employee is performing DNA typing and/or analytical services. The technical leader must review the employment of contract employees by multiple NDIS participating laboratories and/or vendor</p> | |

laboratories for any potential conflicts of interest. If there are no potential conflicts of interest, the technical leader may approve the employment by multiple NDIS participating and/or vendor laboratories. For example, Vendor Laboratory A performs the forensic analysis of DNA samples for State Laboratory Z. An employee of Vendor Laboratory A shall not perform ownership review services for State Laboratory Z on cases that were analyzed by Vendor Laboratory A as this would constitute a conflict of interest.

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Forensic Standard 5.2.6

Database Standard 5.2.6

In a multi-laboratory system, the semi-annual on-site visits are intended to maintain consistency between facilities in the performance of analytical procedures, to ensure proper handling of evidence, and to promote discussion among analysts. The technical leader must demonstrate knowledge and oversight of the DNA program sufficient to ensure that each laboratory is following standards and written protocols.

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Forensic Standard 5.2.7

Database Standard 5.2.7

Newly appointed technical leaders should strive to review validation studies and analytical procedures currently used by the laboratory and educational and training records of currently qualified analysts and technical reviewers at the earliest available time; however, these reviews must be completed and documented within one year of appointment.

If one year has not passed between the appointment of the technical leader and the next audit and the technical leader has not completed the reviews of the validation studies, analytical procedures, and education and training records, then **Standard 5.2.7** is not applicable. In this situation, this standard must be evaluated during the following external audit to ensure that the necessary reviews were completed within one year of appointment.

An acting technical leader that serves in the role for less than one year is not required to complete and document these reviews. The acting technical leader should have sufficient familiarity with the validation studies and analytical procedures to perform the responsibilities of the technical leader for an interim period.

If the technical leader position has not been assumed by a newly appointed technical leader since the last audit, then **Standards 5.2.7, 5.2.7.1 and 5.2.7.2** are not applicable.

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Forensic Standard 5.3

Database Standard 5.3

For a vendor laboratory or a laboratory that is not an NDIS participating lab, **Standard 5.3** and all of its substandards are not applicable.

For a laboratory applying for NDIS participation, **Standard 5.3** and all of its substandards will be assessed but may be not applicable.

All references to CODIS administrator in Standard 5.3 and its substandards are intended to include casework CODIS administrator as applicable.

Latest Revision: 07/01/2020

| Forensic Standards 5.3.1 - 5.3.3 | Database Standards 5.3.1 - 5.3.3 |
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If the minimum education, experience and training qualifications of the CODIS administrator have been reviewed and documented in the Appendix D of two prior external audit documents of the laboratory system where the CODIS administrator is employed, then **Standards 5.3.1 through 5.3.3** do not require review provided that the Appendix D from the past audit documents are available.

An individual appointed as the alternate CODIS administrator after June 1, 2018, will be reviewed in accordance with **Standards 5.3.1 through 5.3.3** and be documented in Appendix D of the Audit Document. The alternate CODIS administrator designation and responsibilities are described in the *NDIS Operational Procedures Manual*.

For **Database Standard 5.3.2**, the CODIS administrator shall be a current or previously qualified forensic or database analyst as defined in **Standard 5.4**; while in **Forensic Standard 5.3.2** the casework CODIS administrator shall be a current or previously qualified forensic analyst as defined in **Standard 5.4**.

For the assessment of **Standards 5.3.1 and 5.3.2**:

- A CODIS administrator appointed prior to July 1, 2009 will be considered compliant with the minimum education and experience requirements of **Standards 5.3.1 and 5.3.2**. This assessment is applicable to the specific laboratory by which the casework CODIS administrator is employed prior to July 1, 2009 and shall not be portable.
- A CODIS administrator appointed on or after July 1, 2009 but before July 1, 2020, must be a current or previously qualified DNA analyst with 3 courses (biochemistry, genetics, and molecular biology) totaling at least 9 cumulative semester hours of laboratory and/or lecture based coursework and coursework or training in statistics and/or population genetics with documented mixture interpretation training to be compliant with **Standards 5.3.1 and 5.3.2**. This assessment is applicable to the specific laboratory by which the CODIS administrator is employed as of July 1, 2020 and shall not be portable.
- A CODIS administrator appointed on or after July 1, 2020 will be evaluated in accordance with the education and experience requirements of **Standard 5.4** and must have documented mixture interpretation training.

If not previously completed and one year has not passed between the appointment of the CODIS administrator and the next external audit and the CODIS administrator has

not completed the FBI's DNA auditor training, then **Standard 5.3.3** is not applicable and must be evaluated during the following external audit to ensure that the necessary training was completed within one year of appointment. If not previously completed and six months have not passed between the appointment of the CODIS administrator and the next external audit and the CODIS administrator has not completed the FBI sponsored CODIS training, then **Standard 5.3.3** is not applicable and must be evaluated during the following external audit to ensure that the necessary training was completed within six months of appointment. A recently appointed CODIS administrator who has not completed the minimum auditor and CODIS training requirements will not be listed in Appendix D until these training requirements are complete.

Latest Revision: 07/01/2020

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| Forensic Standards 5.3.4 – 5.3.5 | Database Standards 5.3.4 – 5.3.5 |
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To successfully satisfy **Standards 5.3.4 and 5.3.5**, the laboratory must document the CODIS administrator's duties, responsibilities and authority.

Latest Revision: 07/01/2020

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| Forensic Standard 5.3.6 | Database Standard 5.3.6 |
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If the CODIS administrator position has not been vacant since the last external audit, then **Standard 5.3.6** is not applicable.

If the CODIS administrator position was vacated but the alternate CODIS administrator (whose designation is described in the *NDIS Operational Procedures Manual*) assumed the CODIS administrator responsibilities, the laboratory may continue to upload DNA profiles to NDIS and **Standard 5.3.6** is not applicable.

If the CODIS administrator position was vacated and the designated alternate CODIS administrator is unable to assume the casework CODIS administrator responsibilities, then the laboratory shall not upload any new profiles to NDIS until a CODIS administrator is appointed.

Latest Revision: 07/01/2020

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| Forensic Standard 5.4 | Database Standard 5.4 |
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Standards 5.4.1 through 5.4.2 will be completed for analysts undergoing their first or second review during an external audit and documented in Appendix D. If the minimum education and experience qualifications of an analyst have been reviewed and documented in the Appendix D of two prior external audit documents of the laboratory system where the analyst is employed, then **Standards 5.4.1 through 5.4.2** do not require review provided that the Appendix D from the past audit documents are available.

The laboratory shall have defined either the date of hire/appointment/promotion or the date of qualification to be used in the evaluation of analyst education, experience and training requirements in accordance with **Standard 4.2**. Regardless of the date used

by the laboratory, the evaluation of an analyst's education, experience and training requirements will not be completed until the analyst is authorized to independently perform assigned job responsibilities.

Latest Revision: 07/01/2020

Forensic Standard 5.4.1

Database Standard 5.4.1

A biology-, chemistry-, or forensic science-related degree must have science and laboratory-based coursework as an integral component. Criminal justice degrees that do not include science coursework (lectures and lab work) are not considered to be forensic science-related degrees.

A variety of college course work may apply toward satisfying this standard and is not limited exclusively to the course titles listed. See guidance under **Standard 5.2.1.2** for additional details on coursework.

| | Minimum Requirements for Biochemistry, Genetics, and Molecular Biology | Minimum Requirements for Statistics and/or Population Genetics |
|--|--|---|
| Appointed/Hired/ Promoted/Qualified on or after July 1, 2020 | 3 courses totaling at least 9 cumulative semester hours of laboratory and/or lecture based coursework | Coursework |
| Appointed/Hired/ Qualified between July 1, 2009 and July 1, 2020 | 3 courses totaling at least 9 cumulative semester hours of laboratory and/or lecture based coursework | Coursework or training* |
| Qualified prior to July 1, 2009 | Coursework [As of July 1, 2004, a minimum of 6 cumulative semester hours was required for those subject areas.] | Coursework or training* |

* The statistics and/or population genetics training requirement could be satisfied through internal or external training. For external statistics and/or population genetics training, a variety of methods may be used, including academic coursework; workshops at local, national, or international meetings or symposia; or other external, technical leader-approved, training courses. The laboratory must maintain documentation of such attendance. Internal statistics and/or population genetics training must be documented.

The DNA training program previously offered by the FBI Laboratory, with graduate credit hours from the University of Virginia, may be applied toward the molecular biology coursework requirement associated with this standard. Unless specifically stated by the FBI, other FBI courses do not fulfill this requirement.

Latest Revision: 07/01/2020

Forensic Standard 5.4.2

An analyst must have a minimum of six months of forensic human DNA laboratory experience gained at a facility where forensic DNA testing was performed for the identification and evaluation of biological evidence in criminal matters. The experience time frame is measured not by the length of time spent with any particular employer but rather by the number of months/years in a position specific for gaining the experience necessary to satisfy this standard. The experience gained by an individual must include the successful analysis of a range of samples typically associated with forensic casework. An individual's participation after appointment or hiring in a formal forensic DNA training program is acceptable for fulfilling or being applied toward fulfilling the experience requirement of this standard.

Refer to **Standard 6** for guidance on the requirements for analyst training.

Latest Revision: 07/01/2020

Database Standard 5.4.2

An analyst must have a minimum of six months of human DNA laboratory experience with at least three (3) months in a forensic or database DNA laboratory. The experience time frame is measured not by the length of time spent with any particular employer but rather by the number of months/years in a position specific for gaining the experience necessary to satisfy this standard. The experience gained by an individual must include the successful analysis of a range of samples typically associated with database analysis. An individual's participation after appointment or hiring in a formal database DNA training program is acceptable for fulfilling or being applied toward fulfilling the experience requirement of this standard.

Refer to **Standard 6** for guidance on the requirements for analyst training.

Latest Revision: 07/01/2020

Forensic Standard 5.5

Database Standard 5.5

Standard 5.5 will be completed for technical reviewers undergoing their first or second review during an external audit and documented in Appendix D.

As defined in **Standard 2**, a technical reviewer is an employee or contract employee who is a current or previously qualified analyst that performs a technical review of, and is not an author of, the applicable report or its contents or the analytical documentation. (Refer to **Standard 2** for analytical documentation.) As such, all analysts that perform technical review must also fulfill the requirements of a technical reviewer. Currently qualified analysts that are authorized to conduct technical reviews will be considered compliant with **Standards 5.5 and 5.5.1** if the requirements of **Standard 5.4** are satisfied. If a laboratory requires additional training and authorization to perform technical reviews, training records for analysts authorized to perform technical review shall be required for **Standard 5.5.2**. If a laboratory authorizes an analyst to perform technical reviews upon completion of the analyst training program, documented training must be included as part of the analyst training records in accordance with **Standard 6.1.3.1**. An analyst qualified prior to July 1,

2020 that is authorized to perform technical reviews will be considered compliant with **Standard 5.5.2**.

Individuals whose sole responsibility is technical review will be evaluated under **Standard 5.5**. For a technical reviewer not previously memorialized in Appendix D as an analyst and/or technical reviewer in the laboratory system being audited, the first and second reviews of the education, experience, and training requirements for the technical reviewer will be documented in Appendix D during two respective external audits. For **Standard 5.5.1**, if the technical reviewer is/was not a qualified analyst in the laboratory system being audited, the technical reviewer must demonstrate that they were previously qualified as an analyst. This may be accomplished through training records, Appendix D from another laboratory, or other documentation from the qualifying laboratory. Appendix D will be completed for technical reviewers that satisfy the education and experience requirements of **Standard 5.4** and the experience and training required under **Standards 5.5.1 and 5.5.2**.

Refer to **Standard 6** for guidance on the requirements for technical reviewer training.

Latest Revision: 07/01/2020

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| Forensic Standard 5.6 | Database Standard 5.6 |
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| Refer to Standard 6 for guidance on the requirements for technician training. | |
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| Latest Revision: 07/01/2020 | |
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| Forensic Standard 5.7 | Database Standard 5.7 |
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| The technical leader must verify the degree obtained and coursework completed for each analyst and technical reviewer. Transcripts and other appropriate documentation must be available to the technical leader for approving an individual's education. | |
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| Latest Revision: 07/01/2020 | |
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Standard 6. Training

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| Forensic Standards 6.1 – 6.1.5 | Database Standards 6.1 – 6.1.5 |
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| To successfully satisfy Standard 6.1 , compliance must be demonstrated with all of the substandards of Standard 6.1 . | |
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| The training program applies to individuals who serve as analysts or technicians in any capacity. The training manual can be designed so that an analyst or technician can be authorized in specific methods, methodologies, or responsibilities independent of the whole manual. | |
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| For Standard 6.1.1 , the training program must address all procedures; however, the laboratory will determine which procedure the analyst or technician will be qualified to perform on casework or on database, known, or casework reference samples. | |
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Any newly validated analytical, interpretation, and/or statistical procedure implemented by the laboratory should be incorporated into the laboratory's training program as soon as practicable.

For **Standard 6.1.2**, practical exercises are not limited to lab work but can also be in the form of data analysis and review. The practical exercises should reflect the extent to which the individual will be trained in an analytical, interpretation, and/or statistical procedure. Examples of a range of samples routinely encountered may include degraded, partial, mixed contributor, low template, off-ladder alleles and microvariant samples.

For **Standard 6.1.3.1**, the training program for an analyst will cover the elements of technical review even if the laboratory requires additional experience or training for an analyst to be authorized to perform technical review. The laboratory can determine when and how analysts are authorized to perform technical reviews and if the analyst will be required to have additional experience or training. For analysts whose sole responsibility will be operating an NDIS approved Rapid DNA System, training in technical review is not required because Rapid DNA analysis does not require human intervention. Refer to **Forensic Standard 6.10/Database Standard 6.8** for authorizations.

For **Standard 6.1.4**, individuals who process forensic, database or casework reference samples may be required to testify in court even if they do not generate a report; therefore, the requirement for an assessment of oral communication skills and/or a mock court exercise applies to analysts and technicians.

For **Standard 6.1.5**, refer to **Standard 6.3** for the required elements of competency testing of trainees. The competency testing must be sufficient for the trainee to demonstrate that he/she has achieved the technical skills and met minimum standards of knowledge necessary to perform the forensic DNA analysis or databasing for which the trainee will be authorized to perform on casework or on database, known, or casework reference samples.

Latest Revision: 07/01/2020

| Forensic Standard 6.2 | Database Standard 6.2 |
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| <p>It is the technical leader's responsibility to evaluate the adequacy of previous training for any individual who has not otherwise completed the laboratory's training program. Modifications to the individual's training based on this evaluation will be approved and documented by the technical leader.</p> <p>Examples may include: the hiring of a fully trained analyst from another laboratory, a technician that is entering the analyst training program, or laboratory support personnel that enter the technician or analyst training program.</p> | |
| Latest Revision: 07/01/2020 | |

| Forensic Standard 6.3 | Database Standard 6.3 |
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| <p>This standard applies to analysts or technicians completing the laboratory's training program who will be authorized to perform independent casework analysis or independent database analysis/processing for the first time as an analyst or technician in the laboratory (e.g., a new hire or a technician promoted to analyst).</p> <p>For Standard 6.3.1, the practical component of competency testing should be relevant to the task(s) that the analyst will be authorized to perform on casework or on database, known, or casework reference samples. The laboratory will determine if the competency testing of a new analyst will also include a written component, an oral component, or both. The competency testing must be sufficient to demonstrate that the trainee has achieved the technical skills and knowledge necessary to perform and explain forensic DNA analysis or DNA databasing.</p> <p>For Standard 6.3.2, the practical component of competency testing should be relevant to the task(s) that the technician will be authorized to perform on casework or on database, known, or casework reference samples. The competency testing must be sufficient to demonstrate that the trainee has achieved the technical skills and knowledge necessary to perform the forensic DNA or DNA databasing methods.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 6.4 | Database Standard 6.4 |
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| <p>This standard will be applicable when an analyst or technician who has completed the laboratory training program is undergoing training in an additional method for which they are not currently qualified or when an analyst or technician is trained in a newly validated and implemented method.</p> <p>For an analyst who also performs technical review, elements of both roles need to be addressed in the training. For example, if the analyst is trained on a new extraction procedure, the analyst should also be familiar with the notes generated during the process that would need to be evaluated during technical review. An additional competency test in technical review is not required.</p> <p>The practical component of competency testing should be relevant to the task(s) that the analyst or technician will be authorized to perform on casework or database samples. Examples of a practical component may include performing the method on a test sample, interpreting data generated by the method, and/or reviewing the notes and/or data generated when performing the method.</p> <p>For personnel intimately involved in a validation, the technical leader may allow the validation to serve as the demonstration of competency. Documentation must be available to indicate that the involvement in the validation was representative of the extent to which the individual will use the method in casework or databasing.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 6.5 | Database Standard 6.5 |
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| <p>This standard will be applicable when a qualified analyst is trained in the interpretation of data using an additional technology, typing test kit, platform, or interpretation software for which they are not currently qualified or when the laboratory analysts are trained in a newly validated and implemented technology, typing test kit, platform, or interpretation software.</p> <p>For an analyst that also performs technical review, elements of both roles need to be addressed in the training. For example, if the analyst is trained on a new typing test kit, the analyst should also be familiar with the notes generated during the data interpretation that would be evaluated during technical review. An additional competency test in technical review is not required.</p> <p>The training for interpretation software pertains to the implementation of new or additional software. The requirements for new or additional interpretation software may not expand to new versions of interpretation software in use in the laboratory. For example, updates or modifications to interpretation software that would not require the analysts to learn new skills and knowledge to interpret data, reach conclusions, or generate reports using that software would not require training under Standard 6.5. However, an updated or modified interpretation software with fundamental changes that requires the analysts to learn new skills and knowledge to interpret data, reach conclusions, or generate reports would require training under Standard 6.5.</p> <p>The practical component should be relevant to the task(s) that the analyst will be authorized to perform on casework or on database, known, or casework reference samples. Examples of a practical component may include interpreting data, performing a statistical calculation, generating a report and/or reviewing the notes and/or data generated with the additional technology, typing test kit, platform, or interpretation software.</p> <p>In instances where the technology, typing test kit, platform, or interpretation software also involve training in a new method(s), both Standards 6.4 and 6.5 will apply to the analyst(s). In these instances, the competency testing may be combined. For example, the analyst may complete a practical competency test by performing the method in the laboratory and interpreting the data and/or generating a report.</p> <p>For personnel intimately involved in a validation, the technical leader may allow the validation to serve as the demonstration of competency. Documentation must be available to indicate that the involvement in the validation was representative of the extent to which the individual will use the method in casework or databasing.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 6.6 | Database Standard 6.6 |
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This standard applies to individuals who will be trained and authorized to conduct technical reviews but are not or will not be authorized as an analyst in the method, technology, typing test kit, platform, or interpretation software (or legacy version). The training is intended to ensure the individual can conduct a technical review of the case notes, data analysis, interpretation, and reports or database processing records, data analysis, and interpretation generated by the laboratory.

This standard does not apply to a laboratory that does not have individuals that solely conduct technical reviews. If the technical reviews in the laboratory are conducted by analysts qualified in the method, technology, typing test kit, platform, or interpretation software (or legacy version) in the laboratory, then **Standard 6.6** will be marked not applicable and these individuals will be evaluated under **Standard 6.5**.

Competency testing for a technical reviewer must establish that the technical reviewer has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform a technical review.

For personnel intimately involved in a validation, the technical leader may allow the validation to serve as the demonstration of competency. Documentation must be available to indicate that the involvement in the validation was representative of the extent to which the individual will use the method in casework or databasing.

Standard 6.6.1.1 is only applicable for an NDIS participating laboratory with contract employee technical reviewers conducting reviews for the NDIS participating laboratory.

Latest Revision: 07/01/2020

Forensic Standard 6.7

This standard applies to analysts who were not previously qualified in the laboratory to interpret data from a legacy technology, typing test kit, and/or platform and will be authorized to reinterpret legacy data.

At a minimum, the training should include a review of the relevant portions of the validation of the legacy procedures and the standard operating procedure(s) relevant to the original interpretation of the legacy data.

The training should address the laboratory's procedures for the reinterpretation of legacy data. (Refer to **Forensic Standard 9.11**)

The practical component of competency testing needs to include interpretation of legacy data but does not require the analyst to generate new data using the legacy technology, typing test kit, and/or platform.

Latest Revision: 07/01/2020

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| Forensic Standard 6.8 | |
| <p>The laboratory procedures must address how analysts and technical reviewers, whose external proficiency testing does not include a legacy technology, typing test kit or platform for which they are qualified or previously qualified, will demonstrate that they maintain or have reestablished the technical skills and knowledge in the reinterpretation of legacy data.</p> <p>For laboratories that do not reinterpret legacy data (refer to Forensic Standard 9.11), this standard is not applicable.</p> <p>Mechanisms for maintaining or reestablishing technical skills and knowledge on a legacy technology, typing test kit and/or platform may include reviewing the validation and standard operating procedures, undergoing training or reviewing previous training, or completing an interpretation competency test.</p> <p>For Forensic Standard 6.8.1, the technical leader must review the documentation that the analyst or technical reviewer completed the elements of the laboratory's procedures and authorize the analyst or technical reviewer to reinterpret legacy data for no more than a two year period.</p> | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 6.9 | Database Standard 6.7 |
| No additional guidance | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 6.10 | Database Standard 6.8 |
| <p>The laboratory must have documentation that provides a formal means for recognizing an individual's successful completion of the training (e.g., certificate, letter, memorandum).</p> <p>Authorization documentation will clearly state the approval to conduct independent forensic DNA analysis or databasing using the applicable methods, technologies, typing test kits, and platforms. The authorization for technical review may be concurrent with authorization as an analyst or a separate authorization but needs to be clearly addressed.</p> <p>The date of authorization of an individual must be documented. The authorization date has particular relevance to proficiency testing requirements discussed in Standard 13 (Proficiency Testing), which requires that newly qualified individuals participate in an external proficiency test within eight months of the authorization date.</p> | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 6.11 | Database Standard 6.9 |
| Laboratory support personnel must have documented training in the laboratory duties they perform. Training should include, at a minimum, those tasks that are necessary | |

for performance of or may impact the results of an analytical procedure (e.g., making reagents or preparing an instrument for operation).

Latest Revision: 07/01/2020

Forensic Standard 6.12

Database Standard 6.10

Retraining of an analyst, technician, or technical reviewer may be necessary as a result of an extended absence from casework or databasing duties, as part of corrective action, or when determined necessary by the technical leader.

The **Forensic Standard 6.12.1/Database Standard 6.10.1** requirement to successfully complete competency testing prior to return to participation in casework or databasing analyses will also apply to individuals who have been on extended leave for a period that takes them out of the proficiency test cycle. The technical leader will determine if the individual requires training or retraining prior to competency testing.

The competency testing should be relevant to the task(s) that the analyst, technician, or technical reviewer will return to performing on casework samples or on databasing, known, or casework reference samples.

Latest Revision: 07/01/2020

Forensic Standard 6.13

Database Standard 6.11

The laboratory must have available for review the training and authorization records for each analyst, technician, and technical reviewer.

The laboratory must have available for review the documented training completed by each laboratory support personnel.

Latest Revision: 07/01/2020

Standard 7. Facilities and Evidence/Sample Control

Forensic Standard 7.1

Database Standard 7.1

To successfully satisfy **Standard 7.1**, the laboratory must demonstrate compliance with all of the substandards of **Standard 7.1**.

Secure, controlled access areas for evidence/sample storage must exist within the laboratory.

The laboratory must be arranged in a way to ensure the integrity of the analyses as described in **Standards 7.1.2** and **7.1.3**.

Through a combination of clearly written analytical procedures, notes, and/or personal observation, the laboratory's approach to evidence/sample processing for PCR-based procedures must demonstrate a separation in time or physical space for each activity.

The laboratory's design must ensure that evidence/sample flow through the various steps of DNA processing does not compromise the integrity of the evidence/sample. The amplification room must be enclosed with walls from the floor to the ceiling and door(s) for passage. The amplification room(s) must physically separate amplified DNA from all other areas of the laboratory by keeping doors in the closed position.

A Rapid DNA instrument/System shall be maintained separate from areas used for evidence examination or sample accessioning. Rapid DNA instrument(s)/System(s) can go in an extraction room, amp setup room, or other area so long as the area where the instrument is maintained is not used for evidence examination or sample accessioning. A Rapid DNA instrument/System shall not be used in rooms containing amplified DNA with the exception of the amplified DNA generated in the Rapid DNA cartridge.

Latest Revision: 07/01/2020

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| Forensic Standard 7.2 | Database Standard 7.2 |
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A laboratory's security system must control access and limit entry to the operational areas. Internal controlled areas shall limit access to only authorized personnel. The distribution system of all keys, combinations, etc. must be current, accurate, clearly documented, and available for review. Many other control systems which include card keys, surveillance cameras, and intrusion alarms, are acceptable when they complement the laboratory's security system by controlling unauthorized access and/or limiting authorized access to the operational laboratory and evidence storage areas.

Latest Revision: 07/01/2020

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| Forensic Standard 7.3 | |
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An evidence control program may be addressed through a single policy/procedure or combination of several policies/procedures. Key components of an evidence control system include proper labeling and sealing of evidence, a documented chain-of-custody record, and a secure area designated for evidence storage.

Latest Revision: 07/01/2020

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| | Database Standard 7.3 |
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A sample inventory control program may be addressed through a single policy/procedure or a combination of several policies/procedures. Key components of a sample inventory control system include labeling, storage, security of samples, documentation of identity, collection and receipt.

A database laboratory that performs known or casework reference sample analysis must have clearly written well-understood procedures that address handling and preserving the integrity of these evidence samples. Key components of such an evidence-control procedure include proper labeling and sealing of evidence, a documented chain-of-custody record, and a secure area designated for evidence storage.

| Forensic Standard 7.3.1 | Database Standard 7.3.1 |
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| <p>Each item of evidence or each database, known, or casework reference sample must be marked with a unique identifier on at least the evidence packaging or sample container.</p> <p>The laboratory must clearly define what constitutes evidence and what constitutes work product because the laboratory may establish different criteria for the handling and control of evidence versus work product. For example, a forensic laboratory may define extracts as evidence and require the extracts be tracked on the chain of custody or a laboratory may define extracts as work product and may not require the extracts be tracked on the chain of custody. If the laboratory retains or returns extract to meet Forensic Standard 7.4.1, the extract shall be treated as evidence.</p> <p>While a databasing laboratory may not receive or process evidence, what constitutes evidence and what constitutes work product must be defined by the laboratory. A database laboratory that processes casework reference samples must define these samples as evidence and ensure the laboratory procedures address proper labeling and sealing of evidence, a documented chain-of-custody record, and a secure area designated for evidence storage as required throughout Standard 7.</p> <p>The laboratory must have a method to distinguish each sample throughout processing; the use of plate or rack mapping may not require the assignment of unique identifiers or individual evidence seals for each sample.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| | Database Standard 7.3.2 |
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| <p>The laboratory shall document the identity, collection, receipt, storage, and disposition of database samples. Documentation may be in hard copy or electronic format.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 7.3.2 | Database Standard 7.3.2.1 |
|---|----------------------------------|
| <p>The chain of custody record must provide a comprehensive, documented history for each evidence transfer over which the laboratory has control. Electronic tracking of evidence is an acceptable alternative to a written record as long as the computerized data are sufficiently secure, detailed, and accessible for review and can be converted to a hard copy when necessary. An electronic equivalent may be used when it can only be applied by the individual for whom the electronic equivalent represents.</p> <p>If the database laboratory is processing casework knowns or reference samples it shall address how it handles the chain of custody for evidence samples and must document all that is listed under Database Standard 7.3.2.1. If the database laboratory does not process casework known or reference samples, Database Standard 7.3.2.1 is not applicable.</p> | |

| Forensic Standard 7.3.3 | Database Standard 7.3.3 |
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| <p>The laboratory must have written procedures that address handling and preserving the integrity of evidence/sample and work product, including known and casework reference samples processed by databasing laboratories.</p> <p>The laboratory may demonstrate compliance with Standard 7.3.3 by specifying short-term and long-term storage that demonstrate proper security. Short-term storage areas may vary from a locked file cabinet to an entire examination room temporarily housing large or bulky items of evidence. The laboratory may not require a container be sealed when testing on the item is in progress.</p> <p>For Forensic Standard 7.3.3.2, the laboratory procedures must define when evidence must be properly sealed. An evidence container is sealed properly if its contents cannot escape readily and if opening the container results in a detectable alteration to the container or seal. The seal must be labeled in a manner that identifies the individual responsible for sealing the evidence. The immediate container need not be sealed (but securely closed) if it is enclosed in a larger container that meets the requirements of a proper seal. In such instances, the container must be closed securely such that its contents are protected from loss, contamination, and/or deleterious change.</p> <p>For Database Standard 7.3.3.1, if the database laboratory processes casework known or reference samples, the laboratory must ensure that samples stored under its custody are properly sealed as described above.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 7.4 | Database Standard 7.4 |
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| <p>The laboratory must have a policy on sample consumption. The policy is expected to provide instruction for if and/or when the laboratory may or may not consume a sample and any documentation that the laboratory requires.</p> <p>If a portion of evidence sample is not available and the laboratory retains or returns extract to meet Forensic Standard 7.4.1, the extract shall be treated as evidence.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 7.5 | |
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| <p>The laboratory policy for the disposition of evidence should address how the disposition will be communicated in the report. (Refer to Forensic Standard 11.2.8)</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

Standard 8. Validation

| Forensic Standard 8.1 | Database Standard 8.1 |
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| <p>To successfully satisfy Standard 8.1, the laboratory must demonstrate compliance with all of the substandards of Standard 8.</p> | |
| <p>The validation studies found to be in compliance with Standard 8.1 and documented in accordance with Standard 15.2.2 after one external audit do not need to be reviewed. If there are no validation studies during the scope of the audit to be evaluated, Standards 8.2 and 8.3 are not applicable.</p> | |
| <p>Additional validation requirements specified in Standard 8 and effective July 1, 2020 are applicable to validations completed on or after July 1, 2020. Validations summarized after September 1, 2011 and prior to July 1, 2020 will need to be evaluated against the 2011 QAS.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 8.2 | Database Standard 8.2 |
|--|-----------------------|
| <p>A DNA laboratory may rely upon another laboratory's developmental validation studies; however, the citations and/or publications referencing that validation must be available and accessible to support the underlying scientific basis. If a laboratory can document the developmental validation through citations and publications, the laboratory will be considered compliant with Standard 8.2.</p> | |
| <p>All validations reviewed and approved during the audit will be documented in Appendix E.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 8.2.1 | Database Standard 8.2.1 |
|--|-------------------------|
| <p>To successfully satisfy Standard 8.2.1, the laboratory must demonstrate compliance with all of the applicable substandards of this standard.</p> | |
| <p>Developmental validation studies are required for all validations being reviewed, regardless of whether they were performed by the laboratory or performed by an external agency (either commercial vendor or another laboratory).</p> | |
| <p>If a laboratory is relying upon an externally performed developmental validation, the citations and publications addressing the elements of Standard 8.2.1 must be available and accessible.</p> | |
| <p>If a laboratory has performed its own developmental validation, it must show evidence of how the elements of Standard 8.2.1 were addressed.</p> | |
| <p>Characterization of the genetic marker: The basic characteristics of a genetic marker must be determined and documented. The basic characteristics may be determined by examining inheritance, mapping, detection and polymorphism(s) of the genetic marker.</p> | |

Inheritance: The mode of inheritance of DNA markers may be demonstrated through family studies

Mapping: Determining the genomic location

Detection: The method for identifying the genetic marker (e.g., capillary electrophoresis, DNA sequencing, hybridization assays)

Polymorphism: Determining the type of variation (e.g., sequence and/or length variants)

Species specificity: The ability to detect genetic information from non-targeted species (e.g., detection of microbial DNA in a human assay) must be determined. The detection of genetic information from non-targeted species does not necessarily invalidate the use of the assay, but may help define the limits of the assay. Species cross-reactivity may be demonstrated using a number of commercially available non-human DNA.

Sensitivity studies: A range of DNA quantities, to include the upper and lower limits of the assay must be evaluated. Sensitivity may be demonstrated utilizing a dilution series of extracted DNA.

Stability studies: Measuring the ability to obtain the results from DNA recovered from biological samples deposited on various substrates and subjected to various environmental and chemical insults should be evaluated. Stability may be demonstrated by titrating commercially available environmental and purification related PCR inhibitors (e.g., hematin, humic acid, tannic acid, EDTA) into extracted DNA or a PCR reaction. For database samples, stability studies may include samples on various substrates and subjected to potential PCR inhibitors (e.g., tobacco) or various storage conditions.

Case-type samples: Case-type samples may be those samples that are from adjudicated cases or mock samples that mimic casework samples. Samples should be representative of items and/or stains typically encountered by the testing laboratory (e.g., blood, semen, saliva, transferred epithelial cells, bones). Samples that mimic casework samples may include samples that are created in the laboratory such as artificially degraded or inhibited samples or mixed DNA samples made from normalized extracted DNA or cell lines.

Database-type samples: Database-type samples may encompass the types of samples (e.g., blood, saliva) and/or sample substrates that are routinely submitted to the database laboratory.

Population studies: The distribution of genetic markers in relevant populations groups must be determined. Population databases must be tested for independence expectations (e.g., Hardy Weinberg Equilibrium and Linkage Equilibrium).

Mixture studies: Mixed DNA samples that are representative of those typically encountered by the testing laboratory must be evaluated. Mixture studies should use

known samples that represent the number of contributors and the range of general mixture types for which the procedure will be used in casework (e.g., mixture proportions, template quantities).

Precision and accuracy studies: Precision and accuracy should address repeatability (i.e., evaluate results of the same instrument and/or operator) and/or reproducibility (i.e., evaluate results among different instruments and/or operators), when practicable. Precision and accuracy may be accomplished by examining the migration and sizing of allelic ladders.

PCR-based studies: Publication of the sequence of individual primers is not required in order to appropriately demonstrate the reliability and limitations of PCR-based technologies. PCR-based studies must include:

- Reaction conditions needed to provide the required degree of specificity and robustness must be determined. These include, but are not limited to, thermal cycling parameters, the concentration of primers, buffers, DNA polymerase, and other critical reagents. Evaluation of the reaction conditions may be demonstrated by amplification of extracted DNA at various thermal cycling parameters, evaluating DNA extracts with primer, buffer, and DNA polymerase concentrations above and below the recommended concentration to assess the impact on peak height balance and PCR artifacts.
- Assessment of differential and preferential amplification measures the specificity and robustness of the PCR reaction. Assessing differential and preferential amplification of the PCR reaction may be demonstrated by amplifying a range of DNA quantities, to include the upper and lower limits of the reaction, to determine the impact on peak height balance between and within a genetic marker. A dilution series of extracted DNA may be used.
- Effects of multiplexing measures the specificity and robustness of the PCR reaction. The effects of multiplexing may be demonstrated by amplification of a range of DNA quantities, to include the upper and lower limits of the reaction, to assess the impact on peak height balance and the presence of PCR artifacts. A dilution series of extracted DNA may be used.
- Assessment of appropriate controls ensures that the method works correctly and ensures the data are valid.
- Product detection studies allow the criteria for the detection of amplified product to be determined based on the platform and/or method used.

A laboratory's internal validation can be used to supplement any elements in which the developmental validation is deficient.

Latest Revision: 07/01/2020

| Forensic Standard 8.2.2 | Database Standard 8.2.2 |
|--|--------------------------------|
| <p>The developmental validation is not required to be published, but publication(s) supporting the underlying scientific principle(s) of a method must be available. Peer reviewed publication (or other means of dissemination to the scientific community, such as presentation at a scientific meeting) of developmental validation studies is encouraged. However, validated technologies or procedures may be implemented without such publication.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 8.3 | Database Standard 8.3 |
|--|------------------------------|
| <p>To successfully satisfy Standard 8.3, the laboratory must demonstrate compliance with all of the applicable substandards of this standard.</p> | |
| <p>Prior to implementing a DNA method, the laboratory must perform an internal validation. The appropriate sample number and the type of samples used in the internal validation studies should be sufficient to support and document the reliability and potential limitations of the method.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 8.3.1 | Database Standard 8.3.1 |
|--|--------------------------------|
| <p>The laboratory shall perform the applicable internal validation studies. Studies determined to be not applicable shall be addressed in the internal validation summaries. (Refer to Standard 8.3.4) A laboratory's internal validation can be used to supplement any studies in which the developmental validation is deficient. If conducted within the same laboratory, developmental validation studies may satisfy some of the elements of the internal validation.</p> | |
| <p>Known and non-probative evidence samples or mock evidence samples: Methods shall be evaluated and tested using known samples and non-probative evidence samples or mock case samples. Mock evidence samples should be reflective of the type and quality expected to be encountered in casework (e.g., various substrates, various stain concentrations). Results from these studies should be compared to the previous results where possible to ensure concordance (i.e., demonstrate agreement between the results obtained compared to those using previous methods or published data). Observed discordance should be documented and, where possible, a reason given for the non-concordance.</p> | |
| <p>Known database-type samples: Methods shall be evaluated and tested using known samples, available database samples, or mock samples. Mock samples should be reflective of the type and quality expected to be encountered in databasing (e.g., various substrates, various stain concentrations). Results from these studies should be compared to the previous results where possible to ensure concordance (i.e., demonstrate agreement between the results obtained compared to those using previous methods or published data). Observed discordance should be documented and, where possible, a reason given for the non-concordance.</p> | |

Precision and Accuracy: Precision and accuracy studies should address repeatability (i.e., evaluate results of the same instrument and/or operator) and/or reproducibility (i.e., evaluate results among different instruments and/or operators), when practicable. Precision and accuracy may be accomplished by examining the migration and sizing of allelic ladders.

Sensitivity and stochastic studies: Sensitivity studies are used to determine the dynamic range, ideal target range, limit of detection, limit of quantification, heterozygote balance (e.g., peak height ratio) and the signal to noise ratio associated with the assay. Sensitivity studies should include a range of template DNA/cellular material that brackets the optimal quantity.

Stochastic studies are used to evaluate excessive random effects (e.g., allele drop-out, peak height imbalance) generally resulting from low quantity and/or low quality samples. Where appropriate to the interpretation model utilized, these studies are used to determine the laboratory's stochastic threshold.

Mixture studies: Mixed DNA samples that are representative of those typically encountered by the testing laboratory shall be evaluated. Forensic mixture studies should use known samples that represent the number of contributors and the range of general mixture types for which the procedure will be used in casework (e.g., mixture proportions, template quantities) and must be used to develop interpretation guidelines.

Contamination assessment: The laboratory shall evaluate the detection of exogenous DNA (e.g., allele drop-in) originating from reagents, consumables, operator and/or laboratory environment using both controls and known samples. The contamination assessment should be used when developing quality control procedures and interpretation guidelines.

Latest Revision: 07/01/2020

| Forensic Standard 8.3.1.1 | Database Standard 8.3.1.1 |
|--|----------------------------------|
| <p>For laboratory systems that consist of more than one laboratory, each of the laboratories must complete and maintain site specific precision, sensitivity, and contamination assessment studies. Remaining validation studies may be shared among all locations in a multi-laboratory system. Summaries of a system's internal validation studies must be available at all sites. Multi-laboratory studies are considered internal validation studies and must be reviewed and approved by the technical leader prior to implementing a procedure in accordance with Standard 8.3.4.</p> <p>A laboratory that relocates to a new facility shall be considered a multi-laboratory system for an audit that spans the relocation period of the two laboratory facilities. As such, the laboratory must complete at a minimum, precision, sensitivity, and contamination assessment studies in the new facility. A summary of the pertinent</p> | |

studies must be written and approval by the technical leader must be documented prior to the initiation of casework or databasing at the new facility.

Latest Revision: 07/01/2020

Forensic Standards 8.3.2 and 8.3.2.1

Validation data must be used to develop quality assurance parameters including: analytical threshold(s) and stochastic threshold(s), where appropriate; evaluating and interpreting DNA typing results (e.g., detecting drop-out, drop-in, or heteroplasmy); evaluating applicable analytical controls; and determining when the DNA typing results are interpretable or uninterpretable.

Validation data must be used to determine the acceptability and interpretation criteria of the analytical controls and necessary standards (i.e., quantification standards, internal size standards) applicable to the method under validation. The validation data must be used to determine the requirements for assessing whether a DNA typing result is consistent with originating from one or more contributors, determining the number of contributors, and discerning major and minor contributors, where appropriate.

Mixed DNA samples that are representative of the number of contributors, DNA mixture ratios, and DNA template input quantities expected to be interpreted by the testing laboratory shall be included in the validation studies used to generate the laboratory's mixture interpretation guidelines.

The validation data must be used to determine the requirements for determining inclusions, exclusions, inconclusive or uninterpretable results. Validation data must be used to support the statistical calculation used on single source and mixed DNA samples. Where statistical thresholds are used to make conclusions for direct comparisons (e.g., inclusion, exclusion), these thresholds must be determined based on validation data. Statistical thresholds may not be applicable to relationship testing in which there are no definite thresholds for determining relatedness.

Latest Revision: 07/01/2020

Database Standard 8.3.2

Validation data shall be used to develop quality assurance parameters including: analytical threshold(s) and stochastic threshold(s), where appropriate; evaluating and interpreting DNA typing results (e.g., detecting drop-out, drop-in); evaluating applicable analytical controls; and determining when the DNA typing results are interpretable or uninterpretable.

Validation data must be used to determine the acceptability and interpretation criteria of the analytical controls and necessary standards (e.g., internal size standards) applicable to the method under validation.

Latest Revision: 07/01/2020

| Forensic Standard 8.3.3 | Database Standard 8.3.3 |
|--|--------------------------------|
| A change in platform instrument model (e.g., to a new capillary electrophoresis instrument model not already in use in the laboratory) requires internal validation. | |
| Latest Revision: 07/01/2020 | |

| Forensic Standard 8.3.4 | Database Standard 8.3.4 |
|---|--------------------------------|
| Summaries must be written for all internal validation studies and include all relevant information to demonstrate that they meet the standards and support the laboratory's interpretation guidelines. Documentation of the validation review and date of approval by the technical leader, prior to implementation in forensic applications, must be maintained. | |
| Latest Revision: 07/01/2020 | |

| Forensic Standard 8.4 | Database Standard 8.4 |
|--|------------------------------|
| <p>Certified reference materials are accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. Examples of certified reference materials include the National Institute of Standards and Technologies (NIST) standard reference material (SRM) for PCR-based DNA profiling (e.g., SRM 2391d and subsequent successors to the 2391 series) and NIST SRM for mitochondrial DNA sequencing (e.g., SRM 2392-I: Human HL-60 DNA).</p> | |
| <p>Laboratories have the option of using a certified reference material or creating a sample traceable to a certified reference material. For a sample to be considered traceable to an appropriate certified reference material the laboratory must demonstrate the proof of homogeneity, stability, and verification of the new lot of the traceable material. The laboratory documentation must detail the preparation, storage, and characterization of the new lot of traceable material.</p> | |
| <p>Laboratories have the option of using additional NIST SRMs (e.g., Human Quantification Standard NIST SRM 2372a) that may be available, but their use is not required by Standard 8.4 unless specifically referenced by the laboratory.</p> | |
| Latest Revision: 07/01/2020 | |

| Forensic Standard 8.5 | Database Standard 8.5 |
|---|------------------------------|
| <p>If a laboratory modifies a procedure in such a way as to alter the validated steps, reagents, or critical instruments, the modified procedure must be evaluated by comparing the original procedure to the modified procedure using similar DNA samples. Modification evaluations must be documented and approved by the technical leader before being implemented in casework or databasing applications.</p> | |
| <p>If the modification has an impact on the efficacy or reliability of the forensic casework or databasing analysis (such as modifications that impact the efficacy of the PCR process or the detection of DNA types), internal validation studies (such as sensitivity</p> | |

and stochastic studies) may be necessary to demonstrate the continued reliability and potential limitations of the method.

Latest Revision: 07/01/2020

Database Standard 8.6

If the NDIS participating laboratory uses an Expert System to enter data directly into CODIS, it shall use an NDIS approved Expert System. Depending on the rule order and set up of Expert System parameters, the laboratory may need to perform developmental validation of that Expert System. Developmental validations of Expert Systems used by NDIS participating laboratories shall be approved by NDIS.

For **Database Standard 8.6.1**, as required by the *NDIS Operational Procedures Manual*, NDIS participating laboratories must recertify their NDIS approved Expert Systems quarterly.

These standards are not applicable for non-NDIS participating laboratories and laboratories that are not using an Expert System.

Latest Revision: 07/01/2020

Forensic Standard 8.6

Database Standard 8.7

A Rapid DNA instrument used for modified Rapid DNA analysis (human interaction) on database, known, or casework reference samples requires validation in accordance with **Standard 8** to ensure the instrument is validated in the laboratory and the interpretation parameters are established for the laboratory in which the instrument will be used.

If a Rapid DNA instrument is used for testing other than that defined as Rapid DNA analysis or modified Rapid DNA analysis, it must be validated in accordance with **Standard 8** for its intended use in the laboratory. If the intended use will include searching or uploading profiles to CODIS, the use must comply with the *NDIS Operational Procedures Manual*.

Latest Revision: 07/01/2020

Forensic Standard 8.7

Database Standard 8.8

An NDIS approved Rapid DNA System does not require a validation because the Rapid DNA System has been extensively validated as part of the NDIS approval process. No changes or modifications are permitted to the (1) Rapid DNA instrument; (2) the chemistries and/or concentrations of the PCR STR typing kit/Rapid DNA cartridge; (3) the settings of the Expert System; or (4) any other software parameters, without NDIS approval as detailed in the *NDIS Operational Procedures Manual*. The performance check is required to ensure the Rapid DNA System is functioning appropriately prior to use. (Refer to **Standard 10.3**)

Latest Revision: 07/01/2020

Forensic Standard 8.8**Database Standard 8.9**

The laboratory must evaluate software to assess the suitability of the software for its intended use in the laboratory. For the purposes of this standard, software includes software tool(s) developed by the laboratory. This evaluation must determine the necessity of validation studies and/or software testing based on how it will be used in the laboratory. As part of the evaluation, the laboratory must determine if the software will be categorized as a component of instrumentation, software used for the analysis and/or interpretation of DNA data, software used for statistical calculations (forensic only), or that the software that does not impact the analytical process, interpretation, and/or statistical calculations.

For commercial off the shelf (COTS) software products (e.g., word processing, electronic spreadsheets, database management) that the laboratory uses to create software tools (e.g., macros, workbooks, databases), the COTS software does not require a developmental validation but the laboratory developed tool must be validated as appropriate for its intended use in the laboratory.

Based on the evaluation the laboratory will determine which studies will be conducted, and these determinations must be documented. If a study or software test is not applicable to the software's intended use in the laboratory and therefore will not be conducted, that information must also be documented.

Any new software or new modules of existing software shall be subjected to the relevant validation studies, as described in **Forensic Standards 8.8.1 and 8.8.2/Database Standards 8.9.1 and 8.9.2.**

Modifications to software shall also be subjected to relevant validation studies and/or software testing as stated in **Forensic Standard 8.8.3/Database Standard 8.9.3.**

The impact of the software on the DNA analysis and/or interpretation process (instrumentation, analysis/interpretation, or statistical calculations) should be considered when designing the appropriate validation studies. Validation studies should also establish the limits of the software use.

Functional testing: Functional testing may include using the software to perform the intended task and ensuring it functions as expected. For example, ensuring that a software tool used to perform a calculation generates the same value as if hand calculated. For a software tool that transcribes or aggregates information from various locations, a functional test may ensure that the expected information is being transcribed or referenced correctly.

Reliability testing: Reliability testing should establish that the software can run in the laboratory's environment. For example, if the laboratory is multi-site, multi-user, or uses a network, the laboratory should ensure that the software functions reliably at each site, for multiple and/or concurrent users, or on the network. Reliability studies should also test the usability limits of the software's functions.

Accuracy and precision studies: Accuracy and precision studies are relevant when measurements and numerical values or calculations are reported. For example, evaluating the accuracy and precision of sizing algorithms when assigning DNA types or the accuracy and precision of a software calculating a random match probability.

Sensitivity studies: Sensitivity studies should evaluate the upper and lower limits of the software. For example, the maximum number of contributors a probabilistic genotyping software can interpret or the dynamic range (i.e., minimum and/or maximum detection) of a typing software.

Specificity studies: Specificity studies are used to evaluate the ability of the system to provide reliable results over a broad variety of typing results (e.g., mixtures, low level profiles). For example, evaluating that a probabilistic genotyping software provides reliable results for contributors and non-contributors.

To assist with software testing, laboratories may consider creating test scenarios or cases that interact with the critical operations of the software or module. Test scenarios or cases can provide a metric for concordance with other methods and/or modified software. These test scenarios or cases may also assist with regression testing.

Latest Revision: 07/01/2020

Forensic Standard 8.8.1

Database Standard 8.9.1

The developmental validation is not required to be published, but publication(s) supporting the underlying scientific principle(s) (e.g., local southern sizing, Markov Chain Monte Carlo) of a method must be available. Peer reviewed publication (or other means of dissemination to the scientific community, such as presentation at a scientific meeting) of developmental validation studies is encouraged. However, validated software may be implemented without such publication.

Not all validation studies are relevant to every type of software. The evaluation of software for its intended use in the laboratory, documented as required by **Forensic Standard 8.8/Database Standard 8.9**, will determine which studies will and will not be conducted.

Latest Revision: 07/01/2020

Forensic Standard 8.8.2

Database Standard 8.9.2

If during the initial evaluation of new software, a laboratory determines a particular module within the software will not be used, validation of that particular module is not required; however, if at a later date, a laboratory decides to use that particular module, an internal validation of the new module of the existing software is required, as applicable.

Refer to **Standard 2** and the guidance in **Forensic Standard 8.8/Database Standard 8.9** for the definitions of and examples for, functional testing, reliability testing, accuracy, precision, and sensitivity and specificity studies.

Not all validation studies are relevant to every type of software. For example, internal validation of data collection software may not require precision studies. The scope of the intended use of the software should dictate the nature of the validation. Validation studies should also establish the limits of the software use.

A laboratory should internally validate new software on systems not part of the laboratory's operational workflow. If this is not feasible, a laboratory should be cautious not to report any data from a system that is currently being internally validated.

For **Forensic Standard 8.8.2.4/Database Standard 8.9.2.4**, LIMS or other inventory/sample tracking software will only require a functional test if it does not impact the analytical process, interpretation, or statistical calculations.

Latest Revision: 07/01/2020

| Forensic Standard 8.8.3 | Database Standard 8.9.3 |
|--|--------------------------------|
| <p>Release notes from software developers can be used to assist in determining if a software modification results in a major or minor revision.</p> <p>Examples of a major revision can include, but are not limited to, modifications of any algorithm, any statistical and/or calculation equation, sequence alignment strategy, data reports, and/or export of results.</p> <p>Examples of a minor revision can include, but are not limited to, cosmetic modifications, improved printing or viewing features, fixing invalid error messages.</p> <p>Forensic Standards 8.8.3.1 to 8.8.3.3/Database Standards 8.9.3.1 to 8.9.3.3: The minimum validation requirements for all major software revisions include functional testing, reliability testing, and regression testing. Refer to Forensic Standard 8.8/ Database Standard 8.9 above for guidance on functional testing and reliability testing.</p> <p>The purpose of regression testing is to ensure that modifications to software have not detrimentally affected any functions of the previously validated software. A laboratory may accomplish regression testing using a set of relevant scenarios run with the original version and the modified software. For example, a laboratory may re-run samples on an instrument with the modified software and compare the new DNA types to the previously generated DNA types. Similarly, a laboratory may opt to re-analyze, re-interpret, and/or re-calculate data using the modified software and compare the output for concordance with previously generated results.</p> | |

A laboratory should test modifications to software on computer systems that are not part of the laboratory's workflow or can temporarily be removed as a part of the laboratory's workflow. If this is not feasible, the laboratory should limit access to the modified software to prevent its use when conducting casework analysis.

Latest Revision: 07/01/2020

Forensic Standard 8.8.4

Database Standard 8.9.4

Reliability testing should establish that the software can run in the laboratory's environment. For example, if the laboratory is multi-site, multi-user, or uses a network, establishing that the software functions reliably at each site, for multiple and/or concurrent users, or on the network. Reliability studies should also test the usability limits of the software's functions.

Latest Revision: 07/01/2020

Forensic Standard 8.8.5

Database Standard 8.9.5

No additional guidance

Latest Revision: 07/01/2020

Forensic Standard 8.9

Database Standard 8.10

Developmental validation studies, internal validation studies, modified procedure evaluations, and software testing, including the approval of the technical leader, shall be retained and available for review for at least as long as the method or software is in use by the laboratory.

Latest Revision: 07/01/2020

Standard 9. Analytical Procedures

Forensic Standard 9.1

Database Standard 9.1

No additional guidance

Latest Revision: 07/01/2020

Forensic Standard 9.1.1

Database Standard 9.1.1

Each procedure must specify the reagents, sample preparation, equipment, and controls used in the analytical process.

The laboratory procedures must be current and readily available.

Latest Revision: 07/01/2020

Forensic Standard 9.2

Database Standard 9.2

To successfully satisfy **Standard 9.2**, the laboratory must demonstrate compliance with all of the substandards of **Standard 9.2**.

Latest Revision: 07/01/2020

Forensic Standard 9.2.1

Database Standard 9.2.1

The procedures for documenting commercial reagents should address what information will be recorded upon receipt of a commercial reagent for quality control and tracking purposes.

The procedures for the formulation of in-house reagents should address the recipe to prepare the reagent and the records that will be retained for quality control and tracking purposes.

Latest Revision: 07/01/2020

Forensic Standards 9.2.2 and 9.2.3

Database Standards 9.2.2 and 9.2.3

If the laboratory has determined an expiration date beyond that provided by the manufacturer, supporting documentation for that date must be available at the laboratory. For those reagents having no expiration date provided by the manufacturer, the laboratory must have a policy or procedure for setting the expiration date.

The laboratory may use an electronic barcoding system to capture the required labeling information. If the laboratory has an electronic barcoding system for the management of its reagents, the name of the reagent must be on the container in addition to the barcoded information.

Latest Revision: 07/01/2020

Forensic Standard 9.3

Database Standard 9.3

The intent of identifying a reagent as a critical reagent is to ensure that the reagent functions correctly prior to its use on samples (e.g., evidence) that may be limited in such a way that the test could not be repeated if the reagent were to fail. For those reagents identified as critical reagents, laboratory procedures must include the quality control measures used for evaluation, the acceptable range of results, procedures for addressing unacceptable data, and mechanisms used for documentation and subsequent approval/rejection of data.

At minimum, the laboratory must identify the reagents listed in **Standards 9.3.1** through **9.3.3** as critical reagents, if used by the laboratory.

For **Standard 9.3.3**, the laboratory must evaluate each new lot of Rapid DNA cartridge, prior to use. A positive sample control shall be processed and analyzed for each new Rapid DNA cartridge lot number, before or in parallel with database, known or casework reference samples analyzed on the Rapid DNA instrument. If a laboratory processes the positive sample control in parallel with reference samples, the data shall only be searched and/or uploaded to CODIS after the controls are interpreted and meet the laboratory's criteria for successful approval of the quality control data. Laboratories must have written procedures for handling data processed in parallel with sample controls, if the control quality data fails.

If test kits or systems for DNA quantification are used for methods other than those performed pursuant to **Forensic Standard 9.4**, these test kits or systems for DNA quantification are not required to be identified as critical reagents.

For laboratories performing Next-Generation Sequencing (NGS), **Standard 9.3.4** will include each new lot of sequencing library preparation reagents and sequencing reagents. A minimum of one positive control or previously characterized DNA sample and one negative control should be sequenced with each new lot of sequencing library preparation reagents and/or sequencing reagents. This can be done separately or in parallel with database, known or casework reference samples. If a laboratory processes the control samples in parallel with reference samples, the data shall only be interpreted, searched and/or uploaded to CODIS after the controls are interpreted and meet the laboratory's criteria for successful approval of the quality control data. Laboratories must have written procedures for handling data processed in parallel with sample controls, if the quality control data fails.

Latest Revision: 07/01/2020

Forensic Standard 9.4

Quantification of forensic and casework reference samples must be assessed prior to nuclear DNA amplification.

“Otherwise calculate” refers to methods, such as cell counting, that are based on empirical data from the sample being typed. “Otherwise calculate” does not include approaches that provide an estimate of DNA quantity based on what is expected for a similar sample type or cutting size, except as provided in **Forensic Standard 9.4.1** for casework reference samples.

For items that are subjected solely to mitochondrial DNA analysis, **Forensic Standard 9.4** is not applicable.

Latest Revision: 07/01/2020

Forensic Standard 9.4.1

Direct amplification and Rapid DNA instruments/Systems are examples of methods that the laboratory could validate that would not require quantification prior to amplification of casework reference samples.

If the laboratory quantifies all DNA samples, **Forensic Standard 9.4.1** is not applicable.

Latest Revision: 07/01/2020

Forensic Standard 9.5

Database Standard 9.4

Forensic Standard 9.5/Database Standard 9.4 and all the substandards do not apply for Rapid DNA instruments/Systems used for Rapid DNA analysis and modified Rapid DNA analysis. Refer to **Forensic Standards 9.7.1.1, 9.7.2, 9.8, and 9.8.1/ Database Standards 9.6.1.1, 9.6.2, 9.7, and 9.7.1** for monitoring the analytical

procedures through the use of analytical controls and standards for Rapid DNA instruments/Systems.

Laboratory procedures must define the acceptable results for standards and controls and document that the standards and controls have been verified as required by **Forensic Standard 9.6.1/Database Standard 9.5.1**.

Latest Revision: 07/01/2020

Forensic Standard 9.5.1

Database Standard 9.4.1

A laboratory must associate at least one reagent blank control with each extraction set or batch of samples, as defined by the laboratory.

The requirements for reagent blank controls specified in **Forensic Standards 9.5.1.1** through **9.5.1.3/Database Standards 9.4.1.1** through **9.4.1.3** are applicable to samples extracted on or after July 1, 2009.

Latest Revision: 07/01/2020

Forensic Standard 9.5.1.1

Database Standard 9.4.1.1

The reagent blank(s) are extracted concurrently with the set or batch of samples, as defined by the laboratory. The extractions must be occurring at the same time to be considered concurrent. For example, consecutive runs on an extraction robot are not considered concurrent.

To achieve the most sensitive conditions, the reagent blanks should be treated in such a way to maximize the detection of potential contamination. For example, if a laboratory has validated eluting its extracted casework evidence samples in various elution volumes, the reagent blank should be eluted in the smallest volume as the samples in the batch or set. For a laboratory that concentrates its extracts, the reagent blank should be eluted in the largest volume prior to concentration.

For direct amplification, if a reagent blank is concurrently used as a negative amplification control and multiple volumes of reagent are concurrently amplified, the laboratory needs to determine the volume(s) of reagent blank(s)/negative amplification control(s) that are needed to be concurrently amplified to meet the sensitivity requirements of **Forensic Standards 9.5.1.1** and **9.5.1.2/Database Standards 9.4.1.1** and **9.4.1.2**.

Latest Revision: 07/01/2020

Forensic Standard 9.5.1.2

Database Standard 9.4.1.2

Amplification using the same sensitivity conditions requires amplifying at least the maximum volume of reagent blank as any associated sample from the extraction batch.

The laboratory analytical procedures (**Standard 9.1.1**) should include the approach to amplification of reagent blanks. If the laboratory extracts multiple reagent blanks, the

procedures should include selecting which blanks to amplify. The laboratory needs to determine the volume(s) of reagent blank(s) that are needed to be amplified to meet the sensitivity requirements of **Forensic Standards 9.5.1.1** and **9.5.1.2/Database Standards 9.4.1.1** and **9.4.1.2**.

The reagent blank is not required to be amplified concurrently with the samples in the associated extraction batch as long as it is amplified using the same typing test kit, instrument model, and sensitivity conditions as the samples within the extraction batch. As required by **Forensic Standard 9.5.3/Database Standard 9.4.3**, a positive and negative amplification control must be included concurrently on each instrument used for amplification.

If a laboratory uses multiple amplification test kits and the laboratory has depleted its reagent blank(s) associated with the extraction set or sample being amplified, a laboratory shall not continue on to a different amplification test kit without a reagent blank.

For a laboratory that extracts multiple reagent blanks within its extraction set, at least one of the reagent blanks must be amplified utilizing the same typing test kit, instrument model, and sensitivity conditions as required by the sample(s). If all reagent blanks are quantified, the laboratory must amplify and characterize at least the reagent blank that demonstrates the greatest signal, if any, in accordance with the laboratory procedures. If a laboratory does not quantify its reagent blanks, at least one reagent blank needs to be amplified in accordance with the laboratory procedure.

For differential extractions that result in a reagent blank control(s) for each fraction, the reagent blank(s) from each fraction will be independently evaluated with the corresponding fraction.

If samples are manipulated after extraction, at least one reagent blank must undergo the same manipulation. For example, if a sample is reconstituted or concentrated, at least one of the reagent blanks associated with that extraction set or batch must also follow through that process. Alternatively, an additional reagent blank(s) may be introduced to control for any subsequent manipulation of sample(s) within the extraction batch as long as an original reagent blank associated with the extraction set and an additional reagent blank are both amplified and typed in accordance with **Forensic Standards 9.5.1.2** and **9.5.1.3/Database Standards 9.4.1.2** and **9.4.1.3**.

If a laboratory determines at the quantification stage to terminate all evidentiary sample processing for a given extraction set, in order to monitor analytical quality, the reagent blank control must be either quantified or typed in order for the evidentiary sample processing to be terminated. In order for a laboratory to determine that evidentiary sample processing is to be terminated after DNA quantification, the laboratory shall have validation data to support that determination.

If the reagent blank is concurrently used as the negative amplification control (e.g.,

direct amplification) the reagent blank must be amplified concurrently on the same instrument using the same typing test kit as the samples. The laboratory needs to determine the volume(s) of reagent blank(s)/negative amplification control(s) that are needed to be concurrently amplified to meet the sensitivity requirements of **Forensic Standards 9.5.1.1** and **9.5.1.2/Database Standards 9.4.1.1** and **9.4.1.2**.

If a laboratory re-amplifies a sample with the same typing test kit and does not increase the template volume over that of the original reagent blank nor alter the amplification parameters to increase sensitivity, then the laboratory does not need to re-amplify the reagent blank associated with the extraction set being re-amplified, provided, however, that the laboratory included amplification positive and negative controls with the extraction set or batch being re-amplified. If a laboratory re-amplifies a sample with the same typing test kit and increases the template volume over that of the original reagent blank, the laboratory needs to re-amplify a reagent blank associated with the extraction set being re-amplified with the increased volume.

Latest Revision: 07/01/2020

Forensic Standard 9.5.1.3

Database Standard 9.4.1.3

If a laboratory injects samples at varying injection times, amplicon volumes, and/or injection voltages, the reagent blank must satisfy the most sensitive injection conditions. For example, if a laboratory uses a five-second injection and a 10-second injection on a sample set, the laboratory must inject its reagent blank with at least the 10-second injection.

If the laboratory increases injection conditions for the samples (including re-amplified samples) the laboratory needs to re-inject a reagent blank associated with the extraction set being re-injected with the increased injection conditions.

Latest Revision: 07/01/2020

Forensic Standard 9.5.2

Database Standard 9.4.2

If the laboratory's validated quantification method allows for the use of a virtual or external standard curve, a calibrator must be run concurrently with the samples. The laboratory procedures should address when reevaluation of the virtual or external standard curve is necessary (e.g., with each new lot of quantification kit).

Latest Revision: 07/01/2020

Forensic Standard 9.5.3

Database Standard 9.4.3

If a batch of samples being typed will be amplified on multiple instruments, each instrument must contain a positive and negative amplification control amplified concurrently using the same typing test kit as the samples on the instrument. If a batch of samples being typed will be amplified with subsequent amplifications on the same instrument, each amplification on that instrument must contain a positive and negative amplification control amplified concurrently using the same typing test kit as the samples on the instrument.

Latest Revision: 07/01/2020

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| Forensic Standard 9.5.3.1 | Database Standard 9.4.3.1 |
| Except as provided in Forensic Standard 9.5.4.1/Database Standard 9.4.4.1 , if a batch of samples being typed was amplified on multiple instruments or multiple amplifications on the same instrument, each positive and negative amplification control shall be typed. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 9.5.4 | Database Standard 9.4.4 |
| The positive and negative amplification controls may also be used as the positive and negative sequencing controls. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 9.5.4.1 | Database Standard 9.4.4.1 |
| Next-Generation Sequencing (NGS) of low-template DNA may be susceptible to crosstalk with the positive amplification control that renders the sample data uninterpretable. In the event that a positive amplification control has a detrimental impact on the integrity of the sample and/or control data, the laboratory must have and follow procedures to monitor the success of the positive amplification control. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 9.5.5 | Database Standard 9.4.5 |
| Allelic ladders and internal size standards must be used to appropriately assign DNA types to the fragments produced in PCR-based systems. Where allelic ladders and internal size standards are not required to assign DNA types, this standard is not applicable. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 9.6 | Database Standard 9.5 |
| To successfully satisfy Forensic Standard 9.6/Database Standard 9.5 , the laboratory must demonstrate compliance with all of the substandards of Forensic Standard 9.6/Database Standard 9.5 . | |
| A laboratory is required to have and follow interpretation guidelines, even if using a validated expert system. The expert system may replace human review for database, known and casework reference samples only. | |
| It is recommended that the laboratory guidelines ensure that, to the extent possible, DNA typing results from forensic samples are interpreted before comparison to any casework reference samples, other than those of assumed contributors. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 9.6.1 | Database Standard 9.5.1 |
| A laboratory shall verify that all quantification standards, internal size standards, allelic ladders and analytical control results meet the laboratory's interpretation | |

guidelines for all reported results. A documented method must exist to demonstrate that control values are verified when used (e.g., check-off, technical review).

The laboratory may use analysis software tool(s) to fulfill the requirement to verify that the internal size standards and allelic ladders produce the expected results as long as the tool is appropriately validated.

Latest Revision: 07/01/2020

Forensic Standard 9.6.2

Database Standard 9.5.2

The laboratory shall define criteria for the interpretation of non-allelic peaks/signal (e.g., stutter, non-templated nucleotide addition, non-specific amplification product, spikes, raised baseline, pull-up or bleed through) specific to the typing test kit and platform used.

Latest Revision: 07/01/2020

Forensic Standard 9.6.3

Database Standard 9.5.3

The laboratory shall define criteria for the interpretation of allelic peaks/signal which addresses interpretation of alleles that fall above the largest or below the smallest allele or virtual bin of the allelic ladder. Where allelic ladders and internal size standards are not required to assign DNA types (e.g., using sequencing platforms), the laboratory shall define the criteria for the interpretation of allelic calls.

The laboratory shall define criteria for the designation of alleles containing an incomplete repeat motif (e.g., an off-ladder allele falling within the range spanned by the ladder alleles or virtual bins).

For mitochondrial DNA analysis via Sanger sequencing, the laboratory shall define criteria to assign nucleotide base calls to appropriate peaks and to determine whether the results are of sufficient quality for interpretation purposes.

Latest Revision: 07/01/2020

Forensic Standard 9.6.4

Database Standard 9.5.4

The laboratory must define the thresholds used for interpretation based on the interpretation model utilized (e.g., binary, probabilistic genotyping). If thresholds are not required by the model utilized, the laboratory must address that thresholds are not used.

A laboratory that uses a threshold-based approach where alleles and genotype combinations for a contributor are either present or absent (i.e., binary) must comply with **Forensic Standards 9.6.4.1** and **9.6.4.2/Database Standards 9.5.4.1** and **9.5.4.2**.

For **Forensic Standard 9.6.4.1/Database Standard 9.5.4.1**, the laboratory shall have and define an analytical threshold to determine the minimum height/magnitude

requirement for distinguishing peaks/signal from background noise. The analytical threshold shall be supported by validation studies.

For **Forensic Standard 9.6.4.2/Database Standard 9.5.4.2**, the laboratory shall have and define a stochastic threshold to define the peak height/signal magnitude value below which it is reasonable to assume that, at a given locus, allelic dropout of a sister allele in a heterozygous pair may have occurred. The stochastic threshold shall be supported by validation studies.

If a laboratory uses measures to enhance the detection sensitivity (e.g., allele height, signal magnitude), additional studies to establish independent criteria for the application of a separate stochastic threshold(s) shall be performed. Such measures may include increased amplification cycle number, increased injection time, and post-amplification purification/concentration of amplified products relative to the laboratory's standard method.

Latest Revision: 07/01/2020

Forensic Standard 9.6.5

Database Standard 9.5.5

A laboratory shall define criteria for determining when DNA typing results are uninterpretable. Uninterpretable DNA typing results may consist of data of limited or poor quality as well as DNA typing results that do not meet the laboratory's quality assurance parameters (e.g., drop-in in an analytical control, data potentially affected by contamination). The laboratory's quality assurance parameters shall be determined based on validation studies.

The laboratory procedures should address conclusions that can be made for uninterpretable data (e.g., data unsuitable for comparisons).

Latest Revision: 07/01/2020

Forensic Standard 9.6.6

The laboratory procedures for mixture interpretation, to include procedures for assigning the number of contributors, discerning major and minor contributors (when applicable), and the criteria for the deduction of a contributor, must be supported by validation studies. Criteria for deducing potential contributors may rely on the assumptions that can be made when formulating conclusions as addressed in the laboratory's procedures for **Forensic Standard 9.10.1**.

Latest Revision: 07/01/2020

Forensic Standard 9.7

Database Standard 9.6

To successfully satisfy **Forensic Standard 9.7/Database Standard 9.6**, the laboratory must demonstrate compliance with all of the substandards of **Forensic Standard 9.7/Database Standard 9.6**.

Latest Revision: 07/01/2020

Forensic Standard 9.7.1

Database Standard 9.6.1

For modified Rapid DNA analysis, the laboratory's guidelines for manual interpretation of data must be supported by validation studies. The laboratory's written guidelines must address handling data processed in parallel with sample controls if the control quality data fails.

For **Forensic Standard 9.7.1.1/Database Standard 9.6.1.1**, the laboratory shall have and follow procedures for the use of internal size standards to monitor the Rapid DNA process. These procedures shall identify the acceptable results for internal size standards and the documented verification of their use.

The laboratory shall have and follow procedures for the use of allelic ladders to monitor the Rapid DNA process. These procedures shall identify the acceptable results for allelic ladders and the documented verification of their use.

The laboratory shall verify that all internal size standards and allelic ladder results meet the laboratory's interpretation guidelines for all reported results. A procedure must exist to demonstrate that the standard values are verified when used (e.g., check-off, technical review).

Latest Revision: 07/01/2020

Forensic Standard 9.7.2

Database Standard 9.6.2

For modified Rapid DNA analysis, the laboratory procedures must address what sample controls, if any, will be used; to include the use of controls that are incorporated by the manufacturer into the Rapid DNA cartridge or if additional controls are processed by the laboratory. The laboratory procedures may establish that positive sample controls and negative sample controls are not incorporated in each run of the Rapid DNA instrument. These laboratory procedures must also address the acceptable results and the documented verification of their use, if applicable.

Latest Revision: 07/01/2020

Forensic Standard 9.8

Database Standard 9.7

For Rapid DNA analysis, the laboratory procedures must address what sample controls, if any, will be used. The laboratory procedures may establish that positive sample controls and negative sample controls are not incorporated in each run of the NDIS approved Rapid DNA System. If applicable, these procedures shall identify the acceptable results for controls and the documented verification of their use.

Latest Revision: 07/01/2020

Forensic Standard 9.9

The laboratory procedures must address the criteria used for the formulation of inclusionary, exclusionary and inconclusive conclusions when comparing a casework reference sample to the data interpreted from a forensic sample.

For example, the procedures could address the use of possible genotype combinations, considering the overall quality of the profile (e.g., degradation,

preferential amplification, inhibition, drop-out), use of assumptions, or other guidance for interpretation beyond solely the presence or absence of alleles.

If the laboratory uses interpretation software (e.g., probabilistic genotyping) to aid in the formulation of conclusions, the procedures must address the use of the software and the interpretation of the statistical results.

For mitochondrial DNA analysis, the laboratory shall define criteria for conclusions based on the evaluation of regions of interpretable sequence and the number of nucleotide base differences. These criteria should address heteroplasmy and homopolymeric cytosine tracts.

Latest Revision: 07/01/2020

Forensic Standard 9.10

The laboratory's procedures shall describe the statistical calculation(s) to be used on single source and mixed DNA samples. The formulae used shall be documented and where applicable, the procedures shall address how to apply statistical calculations for loci that are within the laboratory's stochastic region or for profiles that display stochastic effects.

Refer to **Forensic Standard 11** for the requirements for reporting of results and/or conclusions.

To successfully satisfy **Forensic Standard 9.10**, compliance must be demonstrated with all substandards of **Forensic Standard 9.10**.

Latest Revision: 07/01/2020

Forensic Standard 9.10.1

Laboratory procedure must address what assumptions can be made, or if no assumptions can be made, when formulating conclusions. Any assumptions used when formulating a conclusion (e.g., number of contributors, the presence of a known contributor) shall be documented and supported by the data and case information.

Latest Revision: 07/01/2020

Forensic Standard 9.10.2

The laboratory may determine that inclusions to an expected contributor (e.g., intimate samples, consensual partner) are not relevant in the context of the case.

Latest Revision: 07/01/2020

Forensic Standard 9.10.3

The documentation should be sufficient such that in the absence of the analyst who reports the results and conclusions, another qualified analyst could determine the genetic loci and the assumptions, if applicable, used for the statistical calculation(s). For mitochondrial DNA testing, the genetic loci refers to the mitochondrial DNA regions (e.g., HVI, HVII) used for the statistical calculation(s).

Forensic Standard 9.10.4

The laboratory procedures must address when data determined to be uninterpretable, as required by **Forensic Standard 9.6.5**, will not be used in a statistical calculation. For example, the procedure could address when individual loci are uninterpretable, when a portion of a profile is uninterpretable, or when an entire profile is uninterpretable.

Forensic Standard 9.10.5

The approach used to perform a statistical calculation may include listing the formula(e) used on single source and mixed DNA samples. It also may be accomplished through the description of the statistical software (e.g., PopStats, probabilistic genotyping software) used by the laboratory.

When applicable, the laboratory procedures must address approaches to performing statistical calculations using data determined to be within the laboratory's stochastic region, as required by **Forensic Standard 9.6.4**, or for profiles that display stochastic effects.

For **Forensic Standard 9.10.5.1**, the procedures must address all components of **Forensic Standard 9.10.5.1**. If a laboratory does not perform statistical calculations for biological relationships, the laboratory's procedure is not required to address biological relationships.

For **Forensic Standard 9.10.5.2**, the procedures must address the parameters used for the specific calculations (e.g., upper bounds, confidence interval, counting method, likelihood ratio).

For **Forensic Standard 9.10.5.3**, the laboratory may reference the publication for the population database used for statistical calculations to demonstrate that loci are in Hardy-Weinberg equilibrium and statistically unlinked. For laboratories that use a population database that has not been published (i.e., created internally), the requirements for Hardy-Weinberg and linkage equilibrium may be met by documented independence testing on the population database.

For statistical calculations that do not use the product rule (e.g., lineage marker calculations), **Forensic Standard 9.10.5.3** is not applicable.

The laboratory may apply the product rule when combining autosomal STR, YSTR, XSTR, SNP, or mitochondrial DNA statistical calculations, if shown to be in Hardy-Weinberg equilibrium and statistically unlinked. If independence cannot be demonstrated between the autosomal STR, YSTR, XSTR, SNP, and/or mtDNA results, combining these systems is not recommended.

Forensic Standard 9.10.6

The source of the population database(s) used may be addressed by identifying the name of the database in the procedure.

For laboratories that use published population databases, this may also be accomplished by referencing the publication for the population database used for statistical calculations in the procedure.

Forensic Standard 9.10.7

The source attribution declaration (i.e., identifying the individual as the source of the DNA produced from an evidentiary profile) shall be based on a statistical estimate that meets or exceeds a laboratory defined threshold.

Forensic Standard 9.11

The laboratory procedures must address if the laboratory does or does not conduct reinterpretation of legacy data.

Reevaluating allele calls, genotype calls (to include potential allelic drop-out), a change in the assumptions used, or removing alleles (or entire loci) from statistical estimates from legacy amplification test kit data, are all considered reinterpretation.

The generation of a report for the comparison of two samples as a result of a CODIS high stringency match is not considered reinterpretation of legacy data.

If the interpretation of the DNA profile from a forensic sample has previously been documented regarding the genotypes that would be allowed for possible contributors, that interpretation is not considered reinterpretation.

The laboratory's reinterpretation procedure may direct the analyst to archived procedures used for the interpretation of data at the time of data generation, or the laboratory may create procedures to directly address reinterpretation of legacy data. For example, a laboratory's reinterpretation procedures may include a compilation of previous interpretation procedures and any additional interpretational considerations that had been incorporated by the laboratory (e.g., subsequent revisions to a legacy interpretation procedure) or were developed by reviewing legacy validations (e.g., developing a stochastic threshold when none previously existed).

Refer to **Standards 6.7** and **6.8** for guidance on applicable training and authorization to perform reinterpretation.

| Forensic Standard 9.12 and 9.12.1 | Database Standard 9.8 |
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| <p>The control of contamination includes reducing the possibility of contamination (e.g., by cleaning and decontaminating facilities) and investigating or monitoring potential sources of a detected contaminant. The procedure may also address subsequent action steps or the limitations to the interpretation of data in which contamination was detected.</p> | |
| <p>The procedures used by a laboratory for cleaning and decontaminating facilities and equipment should also address, when appropriate, minimizing surface contamination from samples (e.g., unidentified human remains) prior to sampling.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

Standard 10. Equipment

| Forensic Standard 10.1 | Database Standard 10.1 |
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| <p>To be in compliance with Standard 10.1, the laboratory must use equipment suitable for the methods employed and be in compliance with all standards and substandards of Standard 10.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 10.2 | Database Standard 10.2 |
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| <p>The laboratory must have and follow a program to ensure all critical equipment and instruments are maintained. The laboratory must document the equipment and instruments the laboratory has determined to be critical. If used by the laboratory, the laboratory must include those instruments listed in Standard 10.2.1 and any additional equipment or instrumentation whose accurate functionality directly affects the results of the DNA typing. If the laboratory maintenance program is more stringent than the requirements in Standard 10.3, it must be audited to the more stringent requirements. If the laboratory is in compliance with Standard 10.3 but is not following its own more stringent maintenance program, the finding shall be documented under Standard 10.2 and the applicable substandard(s) of Standard 10.3 (e.g., Standard 10.3.2.8 and/or 10.3.3.6).</p> | |
| <p>For Standard 10.2.1.2, the laboratory must have at least one thermometer that has a certificate that indicates the traceability to national or international standard(s). This thermometer may be used for the performance check of critical equipment (e.g., heat blocks) and/or to ensure the accurate measurements of non-certified thermometers used to monitor temperatures that are critical to the analytical procedures. A certified traceable thermometer may be used to meet this standard for the duration of its certification.</p> | |
| <p>For Standard 10.2.1.9, an example of additional instruments or equipment that produce DNA typing results would include the instruments or equipment used for Next Generation Sequencing.</p> | |

| Forensic Standard 10.3 | Database Standard 10.3 |
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| <p>The laboratory must have procedures for conducting a performance check, for evaluating results (to include the acceptable ranges), for addressing unacceptable data, and for documenting the completion and subsequent approval/rejection of the performance check.</p> <p>Calibration may be utilized as a laboratory defined method to performance check equipment.</p> <p>Procedures for conducting a performance check may be tailored to the purpose of the performance check. For example, a performance check of a new instrument may be different than the performance check for a minor repair to an instrument.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 10.3.1 | Database Standard 10.3.1 |
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| <p>New critical equipment requires a performance check prior to use on casework or for database analysis. If the laboratory defines calibration as the method to performance check equipment, and the new equipment is accompanied by a certificate of calibration, that certification may be used as the initial performance check prior to use. For example, a new pipette received with a valid certificate of calibration may be used without undergoing an additional calibration prior to use.</p> <p>A new instrument of the same model that was previously validated for use in the laboratory requires a performance check prior to use on casework or on database, known, or casework reference samples. For example, a performance check would be necessary if a laboratory currently used one instrument and added another instrument of the same model number.</p> <p>For new critical equipment or instruments that require validation, refer to Standard 8.</p> <p>This initial performance check may be used to meet compliance with Standard 10.3.2 for the current calendar year.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 10.3.2 | Database Standard 10.3.2 |
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| <p>The equipment listed under Standard 10.3.2 requires at least an annual performance check.</p> <p>For Standard 10.3.2.1, the performance check of a handheld pipette may be accomplished by certification by an outside vendor or accomplished in-house through the comparison of a series of predefined measurements. For example, measurements are evaluated at a high and low setting of the pipette's range.</p> | |

For **Standard 10.3.2.2**, the performance check of an incubator or heat block may be accomplished through: (1) certification by an outside vendor; (2) in-house by the comparison of one or more temperature readings at various time intervals against a certified NIST-traceable thermometer; or (3) utilizing a traceable thermometer to monitor the temperature of the incubator or heat block. Incubator/heat blocks used in an analytical procedure includes similarly functioning equipment where the correct temperature reading is pertinent to the analytical procedure (e.g., lysis temperature). Incubator/heat blocks used by the laboratory for analytical purposes shall be distinguishable from those used by the laboratory for only non-analytical purposes. For example, an incubator used to thaw reagents or other non-analytical purposes does not require an annual performance check.

For **Standard 10.3.2.3**, the performance check of a robotic system shall be defined by the laboratory based on its application. For example, the performance check of a robotic system used for pipetting should include a check of the pipetting mechanism, while the performance check of a robotic system used for extraction may necessitate the extraction of a known sample to assess the functionality. The performance check of a robotic system may be accomplished by an outside vendor or in-house by the laboratory.

For **Standard 10.3.2.4**, the performance check of a thermal cycler, including quantitative-PCR, may be accomplished by the system's diagnostic programs and the use of an appropriate certified temperature verification system or process.

For **Standard 10.3.2.5**, the performance check of a thermal cycler temperature verification system may be accomplished through certification by an outside vendor or accomplished in-house by the comparison against a certified thermal cycler temperature verification system.

For **Standard 10.3.2.6**, the performance check of an electrophoresis detection system may be accomplished by analyzing positive controls, internal standards, or using previously characterized DNA samples for comparison. For example, a laboratory may choose to complete the performance check of a Genetic Analyzer by analyzing a set containing an amplification positive control, an amplification negative control and a ladder.

For **Standard 10.3.2.7**, the performance check on any additional instruments or equipment that produce DNA typing results may be accomplished by analyzing positive controls, internal standards, or using previously characterized DNA samples for comparison.

For laboratories performing Next-Generation Sequencing (NGS), **Standard 10.3.2.7** will include the performance check of the NGS system. This may be accomplished by sequencing positive controls or previously characterized DNA samples separately or in parallel with database, known or casework reference samples. If a laboratory processes the control samples in parallel with reference samples, the data shall only

be interpreted, searched and/or uploaded to CODIS after the controls are interpreted and meet the laboratory's criteria for successful approval of the quality control data. Laboratories must have written procedures for handling data processed in parallel with sample controls, if the quality control data fails.

For **Standard 10.3.2.8**, the annual performance check of any additional critical instrument or equipment shall be defined by the laboratory based on its application. If the laboratory does not define any instrument or equipment beyond those listed in **Standards 10.3.2.1** through **10.3.2.7** as requiring an annual performance check, this standard is not applicable.

Laboratories have the option of using an available NIST SRM for a performance check, but their use is not required unless specifically referenced by the laboratory.

Latest Revision: 07/01/2020

Forensic Standard 10.3.3

Database Standard 10.3.3

The critical instruments and equipment identified in **Standard 10.3.3** require additional (beyond annual) performance checks after repair or service. When the repair or service does not directly affect the results of the analysis, a performance check other than that used for the annual performance check may be used. The performance check after repair or service must ensure the repair or service was successful. For example, if a repair to the door on a robotic workstation is made, ensuring the door is properly functioning may be used as the performance check for that repair. This may be accomplished by an outside vendor or in-house by the laboratory.

For laboratories performing Next Generation Sequencing (NGS), **Standard 10.3.3.5** will include the performance check of the NGS system. (Refer to the guidance for **Standard 10.3.2.7**)

For **Standard 10.3.3.6**, the performance check after repair or service of any additional critical instrument or equipment shall be determined by the laboratory based on its application. If the laboratory does not define any instrument or equipment beyond those listed in **Standard 10.3.3.1** through **Standard 10.3.3.5** as requiring a performance check after repair or service, **Standard 10.3.3.6** is not applicable.

Latest Revision: 07/01/2020

Forensic Standard 10.3.4

Database Standard 10.3.4

The minimum requirements for a performance check of an NDIS approved Rapid DNA System upon installation requires running a positive sample control in each sample position prior to the initial use of the Rapid DNA instrument/System for the analysis of database, known or casework reference samples. The laboratory shall identify and document the acceptable results for the positive sample control prior to the use of the Rapid DNA instrument/System.

Latest Revision: 07/01/2020

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| Forensic Standard 10.3.5 | Database Standard 10.3.5 |
| A laboratory must perform a performance check and/or recertify a Rapid DNA instrument/System if the instrument is idle longer than the period recommended in the instrument specifications or as established by the laboratory. If the laboratory determines an acceptable idle time period that exceeds the length recommended by the instrument's specifications, the laboratory must have validation data to support that determination. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 10.4 | Database Standard 10.4 |
| No additional guidance | |
| Latest Revision: 07/01/2020 | |

Forensic Standard 11. Reports

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| Forensic Standard 11.1 | |
| Laboratory case records to demonstrate compliance with this standard may be in hard copy, electronic files, or a combination of both formats. | |
| The laboratory should have a written procedure detailing documentation maintained under this standard. | |
| The laboratory must generate sufficient documentation for each technical analysis to support the reported conclusions such that in the absence of the analyst who reported the analysis, another qualified analyst could evaluate and interpret the resulting data. Documentation must also be sufficient for the completion of a technical review under Standard 12 . | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 11.2 | |
| For Forensic Standard 11.2.2 , sufficient description of the evidence and any sample collected from an item of evidence, when applicable, must be included in the report to allow for the unambiguous identification of the samples tested. Any stain, sample, or item on which an attempt is made to isolate DNA, regardless of the outcome or result, must be addressed in the final report. | |
| For Forensic Standard 11.2.5 , the data generated by the analysis may be considered the results and may include the analyst's evaluation of the results. Conclusions, such as inclusions, exclusions, and other conclusions defined by the laboratory, must be reported for each forensic sample that generated results when applicable casework reference samples are available. Final reports of forensic casework shall address each tested item or its probative fraction. In the case of a | |

differential extraction, the results and/or conclusions for at least the probative fraction must be included in the final report.

For **Forensic Standard 11.2.6**, the quantitative or qualitative interpretation statement provides a weight or additional information to support the conclusion. The use of statistics and/or attribution statements for inclusions (e.g., match, consistent with, cannot be excluded) will be defined by the laboratory. Attribution statements may include a statistically supported source attribution statement, an assumed contributor (for instances where the presence of an individual's DNA on an item is expected), or another qualitative statement as defined by the laboratory.

For **Forensic Standard 11.2.7**, the date of the report must be defined by the laboratory and consistently applied. For example, the date of the report may represent the date the report was drafted, the date the final draft was completed, or the date the report was issued.

For **Forensic Standard 11.2.8**, the disposition of evidence should be specific to the evidence in the report. The disposition may include whether the evidence is returned to the submitting agency, retained by the laboratory, consumed, and/or other wording to convey the status of the evidence at the time of reporting the DNA results. The disposition may be a general statement for all items with the same disposition but must convey the status of each of the items of evidence.

For **Forensic Standard 11.2.9**, one person shall accept responsibility for the content of the report. A secure electronic signature is considered equivalent identification when the laboratory can demonstrate the electronic equivalent can only be applied by the individual for whom it represents. A physical or electronic signature need not be displayed on the report when a secure electronic equivalent is utilized.

Latest Revision: 07/01/2020

Forensic Standard 11.3

The release of database information in **Forensic Standard 11.3** is specifically limited to database applications and does not apply to forensic (anonymous) population databases that are used by casework laboratories to estimate allele frequency information.

Laboratories participating in the National DNA Index System (NDIS) must comply with the provisions limiting access and disclosure to the DNA analyses and DNA samples maintained by federal, state and local criminal justice agencies (and the Secretary of Defense under 10 U.S.C. §1565) in accordance with the Federal DNA Identification Act ('Federal DNA Act'; 34 U.S.C. §12592). The Federal DNA Act provides for limited access to the DNA analyses and DNA samples to the following:

- “(A) to criminal justice agencies for law enforcement identification purposes;
- “(B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;

(C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or
 (D) if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.” 34 U.S.C. §12592(b) (3).

Generally, the state laws on confidentiality will be found in the respective state DNA database laws. Many of the state laws have provisions similar to those in the Federal DNA Act but for states with more expansive access and disclosure laws (such as, humanitarian purposes), the state has agreed, as a condition for its participation in NDIS, to comply with the more restrictive provisions of the Federal DNA Act. For those states having DNA database laws with more restrictive access and disclosure provisions than the Federal DNA Act, laboratories in those states are required to comply with their state laws. A state or local laboratory should have the applicable state laws readily available.

Latest Revision: 07/01/2020

Database Standard 11. Documentation

| | Database Standard 11.1 |
|--|-------------------------------|
| Laboratory database sample records may be in hard copy, electronic files, or a combination of both formats. | |
| The laboratory should have a written procedure detailing documentation maintained under this standard. Materials contained in sample records must demonstrate compliance with this standard. | |
| The laboratory must generate sufficient documentation for each technical analysis to support the interpretation such that in the absence of the analyst who reported the analysis, another qualified analyst could evaluate and interpret the resulting data. Documentation must also be sufficient for the completion of a technical review under Standard 12. | |
| Latest Revision: 07/01/2020 | |

| | Database Standard 11.2 |
|-----------------------------|-------------------------------|
| No additional guidance | |
| Latest Revision: 07/01/2020 | |

| | Database Standard 11.3 |
|---|-------------------------------|
| Laboratories participating in the National DNA Index System (NDIS) must comply with the provisions limiting access and disclosure to the DNA analyses and DNA samples maintained by federal, state and local criminal justice agencies (and the Secretary of Defense under 10 U.S.C. §1565) in accordance with the Federal DNA Identification | |

Act ('Federal DNA Act'; 34 U.S.C. §12592). The Federal DNA Act provides for limited access to the DNA analyses and DNA samples to the following:

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- (B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;
- (C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or
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Generally, the state laws on confidentiality will be found in the respective state DNA database laws. Many of the state laws have provisions similar to those in the Federal DNA Act but for states with more expansive access and disclosure laws (such as, humanitarian purposes), the state has agreed, as a condition for its participation in NDIS, to comply with the more restrictive provisions of the Federal DNA Act. For those states having DNA database laws with more restrictive access and disclosure provisions than the Federal DNA Act, laboratories in those states are required to comply with their state laws. A state or local laboratory should have the applicable state laws readily available.

The laboratory procedure for the release of personally identifiable information in connection with a database hit shall be compliant with the *NDIS Operational Procedures Manual*.

Latest Revision: 07/01/2020

Standard 12. Review

Forensic Standard 12.1

This standard is intended for data generated within the DNA laboratory. **The review of data generated external to the laboratory is governed by Standard 17.**

The laboratory shall have a written procedure detailing the elements of its technical and administrative review including how the completion of the technical and administrative review will be documented. The laboratory may address the elements of technical and administrative review through a single procedure or a combination of several procedures. The laboratory’s technical and administrative review of forensic casework must include the elements in **Forensic Standards 12.2 and 12.3.**

The laboratory must conduct and document both administrative and technical reviews of all case files and reports prior to issuing the report.

Latest Revision: 07/01/2020

| | Database Standard 12.1 |
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| <p>This standard is intended for data generated within the DNA laboratory. The review of data generated external to the laboratory is governed by Standard 17. The laboratory must have written procedures defining the elements associated with both technical and administrative reviews.</p> | |
| <p>NDIS participating laboratories must have and follow procedures for reviewing database matches including the verification and resolution of the matches. If a database laboratory issues reports, both technical and administrative reviews are required. Notification letters issued in the course of a database hit which do not contain technical data require, at a minimum, an administrative review.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 12.1.1 | Database Standard 12.1.1 |
|---|---------------------------------|
| <p>The individual conducting technical reviews must be qualified as an analyst or a technical reviewer in the method, technology, typing test kit, platform, and interpretation software that the review encompasses and undergo semi-annual proficiency testing. The technical reviewer shall not be the original analyst.</p> | |
| <p>An analyst proficiency tested in accordance with Standard 13 can serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.</p> | |
| <p>The administrative reviewer is not required to be a current or previously qualified DNA analyst or a technical reviewer.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 12.2 | |
|--|--|
| <p>Laboratory procedures must describe the method used for documenting the completion of the technical review.</p> | |
| <p>For Forensic Standard 12.2.2, the laboratory may use analysis software tool(s) to review internal lane standards and allelic ladders to verify that the expected results were obtained as long as the laboratory's validation of the software tool(s) demonstrates that the software appropriately applies the laboratory's interpretation guidelines. The technical reviewer would then ensure that the expected results had been verified.</p> | |
| <p>Forensic Standard 12.2.7 and its substandards are not applicable for non-NDIS participating laboratories.</p> | |
| <p>For laboratories with an LDIS casework component, prior to the upload or search of a profile at SDIS, DNA profiles must be verified by another qualified analyst or technical reviewer for eligibility for CODIS, correct DNA types, and appropriate specimen</p> | |

category.

For SDIS laboratories without an LDIS casework component, prior to the search of a profile at SDIS or entry of a profile into a searchable category at SDIS, the eligibility for CODIS, correct DNA types, and appropriate specimen category must be verified by another qualified analyst or technical reviewer.

Forensic Standard 12.2 and its substandards do not apply for laboratories using an NDIS approved Rapid DNA System on casework reference samples but do apply to laboratories using Rapid DNA instruments to perform modified Rapid DNA analysis on casework reference samples.

Latest Revision: 07/01/2020

Database Standard 12.2

Laboratory procedures must describe the method used for documenting the completion of the technical review. The laboratory's technical review procedures for database samples must include each of the elements in **Database Standards 12.2.1** through **12.2.3**. The review of the DNA types may be accomplished by an NDIS approved and internally validated expert system.

A documented technical review of the data must be completed by the NDIS participating laboratory prior to uploading or searching the data at SDIS. **Database Standard 12.2** and its substandards do not apply for laboratories using an NDIS approved Rapid DNA System but do apply to laboratories using Rapid DNA instruments to perform modified Rapid DNA analysis.

Latest Revision: 07/01/2020

Forensic Standard 12.3

Laboratories must describe the method used for documenting the completion of the administrative review. The laboratory's administrative review procedures of forensic casework must include the elements in **Forensic Standards 12.3.1** and **12.3.2**.

Laboratories that include some or all of the administrative review elements listed in **Forensic Standard 12.3** in their technical review procedure also must document the completion of the administrative review. The technical and administrative review may be accomplished by a single qualified individual.

The review of the chain of custody and disposition of evidence may be limited to the items received by the laboratory. At a minimum, the review should ensure the chain of custody supports the reported disposition of the evidence.

Latest Revision: 07/01/2020

Database Standard 12.3

The laboratory's administrative review procedures of database hit correspondence must include the elements in **Database Standards 12.3.1** through **12.3.3**.

Laboratories must describe the method used for documenting the completion of the administrative review. Laboratories that include some or all of the administrative review elements listed in **Database Standard 12.3** in their technical review procedure also must document the completion of the administrative review. The technical and administrative review may be accomplished by a single qualified individual.

The review of the chain of custody and disposition of evidence may be limited to the known or casework reference samples received by the DNA database laboratory.

Latest Revision: 07/01/2020

Forensic Standard 12.4

Database Standard 12.4

The laboratory must have and follow a documented policy and/or procedure that defines the course of action necessary in the event of an unresolved discrepant conclusion or interpretation.

Latest Revision: 07/01/2020

Forensic Standard 12.5

Forensic Standard 12.5 is not applicable for non-NDIS participating laboratories.

Latest Revision: 07/01/2020

Database Standard 12.5

Database Standard 12.5 is not applicable for non-NDIS participating laboratories.

Latest Revision: 07/01/2020

Standard 13. Proficiency Testing

Forensic Standard 13.1

Database Standard 13.1

Each analyst, technical reviewer, technician, and other personnel designated by the technical leader shall undergo semi-annual proficiency testing in accordance with **Standards 13.1.1** through **13.1.6**. Semi-annual requires testing to take place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year, and where the interval between events is at least four months and not more than eight months. The date used for tracking compliance with this standard is as defined by **Standard 13.3**.

Individuals who have been on leave for a period that takes them out of the proficiency test cycle, must comply with **Forensic Standard 6.12.1/Database Standard 6.10.1** prior to resuming casework or databasing and then return to the proficiency testing cycle within eight months.

Proficiency testing requirements do not apply to the use of a Rapid DNA System; however, analysts qualified to perform modified Rapid DNA analysis must be proficiency tested in accordance with **Standard 13.1.2.1**.

Latest Revision: 07/01/2020

Forensic Standard 13.1.1

Database Standard 13.1.1

If the analyst is qualified in only one technology then the analyst will take both semi-annual tests in that technology. All applicable samples in a single proficiency test shall be worked for each technology. It is permissible for multiple technologies to be reported on a single proficiency test. Alternatively, an analyst qualified in multiple technologies may be separately tested in each technology. For example, a laboratory may administer one test in the first half of the year with their YSTR technology and one test in the second half of the year with their autosomal STR technology.

Latest Revision: 07/01/2020

Forensic Standard 13.1.1.1

Database Standard 13.1.1.1

The applicable CODIS core loci or CODIS core sequence ranges shall be attempted for the applicable technology at least once per year. For example, if the laboratory is testing the STR technology, the 20 CODIS core loci must be attempted at least once per year. If the laboratory is testing the mitochondrial DNA technology, at minimum the NDIS accepted sequence ranges of 73-340 and 16024-16365 must be attempted at least once per year. For the YSTR, XSTR, and SNP technologies, there currently is not an NDIS defined set of CODIS core loci.

Latest Revision: 07/01/2020

Forensic Standard 13.1.2

Database Standard 13.1.2

If the analyst is qualified in only one typing test kit then the analyst will take both semi-annual tests with that typing test kit. An analyst qualified to use multiple typing test kits for casework or database examinations may be separately tested using each typing test kit. For example, a laboratory that uses 2 different kits for the STR technology may administer one test with their STR Kit #1 and one test with their STR Kit #2 provided that STR Kit #1 and/or STR Kit #2 include the 20 CODIS core loci as required by **Standard 13.1.1.1**.

Latest Revision: 07/01/2020

Forensic Standard 13.1.2.1

Database Standard 13.1.2.1

If the analyst is qualified to perform modified Rapid DNA analysis with a Rapid DNA instrument model and the instrument compatible Rapid DNA cartridge contains different PCR STR typing test kits, then data generated by each PCR STR typing test kit must be tested at least once per year. If the analyst is qualified to perform modified Rapid DNA analysis with multiple Rapid DNA instrument models using the same or different PCR STR typing test kits on the Rapid DNA cartridges, then data generated by each PCR STR typing test kit on each instrument model must be tested at least once per year.

Proficiency testing requirements do not apply to the use of a Rapid DNA System.

Latest Revision: 07/01/2020

| Forensic Standard 13.1.3 | Database Standard 13.1.3 |
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| <p>Standard 13.1.3 applies to analysts, technicians, and other personnel designated by the technical leader who perform analytical procedures on forensic, database, known or casework reference samples. The laboratory documentation shall demonstrate that each individual has performed at least one method in each methodology for which they are qualified to perform casework or database examinations at least once per year. For example, if an analyst is qualified to perform 3 different extraction methods (e.g., two robotic methods and a manual method), the analyst must extract on a proficiency test at least once per year but the laboratory may determine which of the extraction methods will be used.</p> | |
| Latest Revision: 07/01/2020 | |

| Forensic Standards 13.1.4 and 13.1.4.1 | Database Standards 13.1.4 and 13.1.4.1 |
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| <p>The individual need not perform every methodology on a single test when performed in accordance with Standard 13.1.4.1. For laboratories that employ technicians and/or use a team approach (i.e., multiple analysts/technicians are involved in the laboratory processing of a sample or case) in accordance with Standard 13.1.4.1, a methodology may be performed by a technician or another analyst. For example, for a laboratory whose analysts perform all methodologies and utilize technicians, the analysts may perform extraction on one test and utilize a technician to perform the extraction on the second test in a year. The individual(s) that participate on each test must be tracked to demonstrate compliance with Standard 13.4.2; however, only one analyst will be assigned to and responsible for completing the interpretation of test sample data and reporting the results for submission to the proficiency test provider. Each participant will be informed of the results of the evaluation of their test(s) in accordance with Standard 13.6.1.</p> | |
| Latest Revision: 07/01/2020 | |

| Forensic Standard 13.1.5 | Database Standard 13.1.5 |
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| <p>Individuals whose sole responsibility is technical review shall be proficiency tested in accordance with Standard 13.1.5 and the applicable substandards.</p> | |
| <p>Technical reviewers that are qualified to review data from multiple technologies or typing test kits shall be proficiency tested in technical review of each technology and typing test kit at least once a year. Technical reviewers that are qualified to review data from a single technology or typing test kit shall be proficiency tested semi-annually in technical review of data from that technology and typing test kit.</p> | |
| <p>An analyst proficiency tested in the specific technology may serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.</p> | |
| Latest Revision: 07/01/2020 | |

| Forensic Standard 13.1.5.1 | Database Standard 13.1.5.1 |
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| <p>Refer to the guidance for Standard 13.1.1.1</p> | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 13.1.5.2 | Database Standard 13.1.5.2 |
| Refer to the guidance for Standard 13.1.2.1 | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 13.1.5.3 | Database Standard 13.1.5.3 |
| <p>The contract employee performing technical reviews must be administered a proficiency test by an NDIS participating laboratory. The contract employee performing technical review may be administered a proficiency test by the NDIS laboratory or by another NDIS participating laboratory. If the contract employee performing technical review completes a proficiency test for another NDIS participating laboratory, the technical leader of the NDIS participating laboratory for which the technical reviewer is under contract to conduct reviews shall review and approve the proficiency testing administered by the other NDIS participating laboratory. For example, if a technical reviewer is a contract employee of NDIS Lab A and NDIS Lab B, the contract employee performing technical review may take a proficiency test for NDIS Lab A and NDIS Lab B or may take a proficiency test for NDIS Lab A and provide that proficiency test to the technical leader of NDIS Lab B. The technical leader of NDIS Lab B must review and approve that proficiency test.</p> | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 13.1.6 | Database Standard 13.1.6 |
| <p>A newly qualified individual shall undergo external proficiency testing within eight months of their qualification date. The date used for tracking compliance with this standard is as defined for Standard 13.3. An individual will be considered in compliance with the semi-annual proficiency testing requirement (Standard 13.1) if the initial proficiency test is taken within 8 months of qualification. For example, an analyst qualified in December is permitted to wait until July to enter the proficiency testing cycle. The individual is required to be in compliance with the applicable requirements of Standards 13.1.1 through 13.1.5 in the next full calendar year.</p> | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 13.2 | Database Standard 13.2 |
| <p>The laboratory must not have access to the proficiency test results until all participants have completed the test.</p> <p>A laboratory that is participating in a proficiency test provider's pre-distribution program may count the pre-distribution tests as one of the two external proficiency tests for the calendar year. To comply with Standard 13.2, the laboratory must resubmit the pre-distribution test results during the general distribution testing phase for that specific test in order to be included in the provider's published external summary report. The pre-distribution test will be considered received, assigned, submitted, or due with the general distribution testing phase of the proficiency test in accordance with Standard 13.3. For example, if the laboratory uses the assigned</p> | |

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| date for tracking purposes, the pre-distribution test will be given an assigned date when the general distribution testing phase commences. |
| Latest Revision: 07/01/2020 |

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| Forensic Standard 13.3 | Database Standard 13.3 |
| No additional guidance | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standards 13.4 – 13.4.7 | Database Standards 13.4 – 13.4.7 |
| No additional guidance | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 13.5 | Database Standard 13.5 |
| To satisfy Standard 13.5 , the laboratory must evaluate external proficiency test results to demonstrate compliance with each of the substandards of Standard 13.5 . The laboratory's evaluation criteria must include each of the substandards under Standard 13.5 such that the evaluation criteria may be assessed even if a criteria was not applicable during the evaluation of proficiency test results during the scope of the audit. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standards 13.5.1 – 13.5.3 | Database Standards 13.5.1 – 13.5.2 |
| No additional guidance | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 13.5.3.1 | |
| The technical leader review of any inconclusive conclusion for compliance with laboratory guidelines may be part of the evaluation of proficiency test results or have occurred prior to submission of the proficiency test and the documentation will be reviewed during the evaluation of proficiency test results. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 13.5.4 | Database Standard 13.5.3 |
| A satisfactory grade is attained for a proficiency test when there are no analytical errors for the DNA typing data or reported conclusions. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 13.5.4.1 | Database Standard 13.5.3.1 |
| All discrepancies or errors, to include the occurrence of administrative errors, and subsequent corrective actions, as applicable, shall be documented. Non-administrative discrepancies and errors will be handled in accordance with Standard 14 . | |
| The laboratory should not wait for correspondence from an accrediting body's proficiency review committee when evaluating proficiency tests or investigating | |

potential discrepancies or errors. Proactive investigation and subsequent communication with an accrediting body's proficiency review committee could eliminate or expedite the closure of inquiries that result from an accrediting body's observation of a possible discrepancy or error. Correspondence with an accrediting body's proficiency review committee should be retained as documentation under **Forensic Standard 13.5.4.1/Database Standard 13.5.3.1**.

Latest Revision: 07/01/2020

Forensic Standards 13.6 – 13.6.3

Database Standards 13.6 – 13.6.3

No additional guidance

Latest Revision: 07/01/2020

Standard 14. Corrective Action

Forensic Standards 14.1 and 14.1.1

Database Standards 14.1 and 14.1.1

The laboratory policy and/or procedure must address, at a minimum, nonconformities resulting from casework or database analysis, proficiency tests, testimony and audits. Nonconformities not requiring a corrective action plan may be remediated with documented correction or other documentation. A corrective action plan that is developed to evaluate and remediate the nonconformity, must be documented and include the elements listed in **Standard 14.2**.

Latest Revision: 07/01/2020

Forensic Standard 14.2

Database Standard 14.2

The goal of the corrective action plan is to identify, correct, and/or prevent reoccurrence of the nonconformity, when possible. The identification of the cause(s) of the nonconformity may include a root cause analysis. Corrective actions are intended to remediate the nonconformity with time frames to ensure appropriate response to the nonconformity. Preventive measures are intended to minimize the potential reoccurrence of the nonconformity in the future.

For **Standard 14.2.1**, the corrective action plan requires the approval of the technical leader before implementation. If necessary, the technical leader has the authority to initiate, suspend, and resume technical operations for the laboratory or an individual. (Refer to **Standard 5.2.5.2**)

For **Standard 14.2.2**, **Standard 5.3.4.4** requires the CODIS administrator to ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures; the CODIS administrator must be notified when the nonconformity impacts DNA records entered into CODIS. If necessary, the CODIS administrator may terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified in accordance with **Standard 5.3.5**.

Latest Revision: 07/01/2020

Standard 15. Audits

| Forensic Standard 15.1 | Database Standard 15.1 |
|---|------------------------|
| <p>The required annual audit shall, at a minimum, occur once every calendar year and shall be at least 6 months but no more than 18 months apart. Annual audits may be conducted in an internal and/or external manner and, at the discretion of the laboratory, may consist exclusively of external audits or be performed on more than an annual basis.</p> <p>The audit must entail the review of documentation since at least the last annual audit to assess compliance to the standards. The scope will be expanded to at least the last external audit, for the assessment of compliance to the standards for personnel, training, and validation. (Refer to Standards 15.2.1, 15.2.1.1, and 15.2.2)</p> <p>In accordance with Standard 15.4, only audits that were performed using the current (as of the time of the respective audit) FBI Quality Assurance Standards Audit Document shall be eligible for compliance with Standards 15.1 and 15.2.</p> <p>For laboratories undergoing their first external QAS audit, the audit being conducted should be used to assess Standards 15.2 and 15.4; however, the remaining substandards of Standard 15 may not be applicable.</p> | |
| Latest Revision: 07/01/2020 | |

| Forensic Standard 15.2 | Database Standard 15.2 |
|---|------------------------|
| <p>For Standards 15.2 and 15.3, Appendix C will be used to document the self-verification by the auditor(s) to ensure that the audit team consists of appropriately qualified individuals. This verification should be documented and obtained prior to the beginning of the audit and maintained by the laboratory.</p> <p>The auditor(s) from the second agency(ies) must have successfully completed the FBI's DNA auditor training course. For the external audit, it is the laboratory's responsibility to ensure that there is at least one person who is, or has previously been, a qualified analyst for each specific DNA technology performed and platform used. This may be accomplished by having a single auditor who meets all of the specified qualifications or through a combination of the various members of a multi-person audit team.</p> <p>Standard 15.2 requires that an external audit be performed at least once every two years and Standard 15.5.2 requires that all external audits performed on an NDIS laboratory, regardless of frequency, shall be submitted to the NDIS Custodian. If an external audit to fulfill Standard 15.2 does not meet the timing requirements of Standard 15.1 (i.e., occurs less than 6 months or more than 18 months from the</p> | |

laboratory's previous annual audit), the NDIS Custodian should be contacted for additional guidance.

In accordance with **Standards 15.2.1** and **15.2.2**, when documentation of the required reviews has been memorialized in previous external audit documents, the auditor(s) is not required to perform additional review with respect to the personnel or validations that were previously reviewed and documented; however, this in no way prohibits the auditor from performing such additional reviews as that auditor(s) may deem appropriate or necessary.

Latest Revision: 07/01/2020

Forensic Standard 15.2.1

Database Standard 15.2.1

For **Standard 15.2.1**, the date defined by the laboratory according to **Standard 4.2** will be used for determining the applicable version of the standards for evaluating the education, experience and training requirements. Approval of the education, experience and training qualifications will be documented in Appendix D for two successive, separate external audits.

The two independent external auditor approvals of personnel referenced in **Standard 15.2.1** are not transferable and are only valid within the laboratory or laboratory system for which those personnel are employed at the time of the approvals.

For **Standard 15.2.1.1**, training qualifications for the laboratory's analysts/technical reviewers in an additional technology(ies), typing test kit(s), or platform(s) will be evaluated in accordance with **Standards 6.5, 6.6** and/or **6.7**. A CODIS administrator or technical leader who performs the role of analyst or technical reviewer will also have training qualifications in an additional technology(ies), typing test kit(s), or platform(s) evaluated in accordance with **Standards 6.5, 6.6**, and/or **6.7**. Approval of the additional training qualifications will be documented in Appendix D for one external audit.

For the documentation of analysts in Appendix D, the first and second external reviews of each analyst's education and experience requirements listed in **Standards 5.4.1** and **5.4.2**, and completion of the analyst's initial training as required by **Standard 6.1** will be documented. Additionally, analysts that receive additional training in a technology (e.g., STR, YSTR, mitochondrial DNA), typing test kit, or platform as required by **Standard 6.5** will be documented. Additional training in a new method other than a technology, typing test kit or platform (e.g., extraction method A, quant method B) as described in **Standard 6.4**, does not require documentation in Appendix D. For analysts that are under review for additional training, the auditor does not need to review education, experience, and initial training that was previously memorialized in the Appendix D of a past external audit document.

A technical reviewer, who is a currently or previously qualified analyst in the laboratory, does not need to be separately listed in Appendix D as a technical reviewer. A technical reviewer who is not currently or previously qualified as an

analyst in the laboratory for which they are performing technical reviews must have their education, experience, and training in the laboratory, as described in **Standard 6.6**, reviewed and be memorialized in Appendix D.

To aid the audit team in determining who requires these independent external reviews, the laboratory should generate a list of analysts/technical reviewers who have completed the initial training and require a first or second external review and a list of analysts/technical reviewers who have completed additional training in a technology, typing test kit or platform whose additional training requires review.

The CODIS administrator and alternate CODIS administrator (as required by the *NDIS Operational Procedures Manual*) need to be reviewed to ensure compliance with the education, experience and training requirements listed in **Standards 5.3.1, 5.3.2, and 5.3.3**. A CODIS administrator who is also an analyst or technical reviewer undergoing a first or second external review will be listed independently in the Analyst/Technical Reviewer sections and the CODIS administrator sections. A recently appointed CODIS administrator who has not completed the minimum CODIS training requirements, as in **Standard 5.3.3**, will not be listed in Appendix D until the CODIS training requirements are complete.

The Technical Leader's education and experience will be reviewed as required by **Standards 5.2.1 and 5.2.2**. A Technical Leader is required to have completed technology training, if required per **Standard 5.2.3**, or DNA Auditor Training, as required by **Standard 5.2.4**, to be memorialized during the first external review. A recently appointed Technical Leader who has not completed the minimum training requirements, as in **Standard 5.2.3**, if applicable, and **Standard 5.2.4**, will not be listed in Appendix D until the training requirements are complete.

Latest Revision: 07/01/2020

Forensic Standard 15.2.2

Database Standard 15.2.2

Standard 15.2.2 is only applicable to those methods that are currently used by the laboratory. Approval of the validations will be documented in Appendix E for one external audit. The training associated with the implementation of a newly validated technology(ies), typing test kit(s), or platform(s) will be documented in accordance with **Standard 15.2.1.1**, as applicable.

If the entirety of a validation is not approved (e.g., due to a finding under a specific section of **Standard 8**), the partial approval may be documented in Appendix E. This will allow the subsequent external audit team to complete and document the completion of the remaining validation studies.

Appendix E may also be used to document the review and approval of additional studies, such as modified procedure evaluations or software testing.

Latest Revision: 07/01/2020

| Forensic Standard 15.3 | Database Standard 15.3 |
|---|------------------------|
| <p>Appendix C will be used to document the self-verification to ensure that the audit team consists of appropriately qualified individuals. This verification should be maintained by the laboratory.</p> | |
| <p>The audit team must include at least one auditor who has successfully completed the FBI's DNA auditor training course. It is the laboratory's responsibility to ensure that there is at least one person on the audit team who is, or has previously been, a qualified analyst for each specific DNA technology performed and platform used. This may be accomplished by having a single auditor who meets all of the specified qualifications or through a combination of the various members of a multi-person audit team.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 15.4 | Database Standard 15.4 |
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| <p>The Audit Documents for Forensic DNA Testing Laboratories and DNA Databasing Laboratories correspond to the standards in effect at the time of the audit. Additionally, this QAS Guidance Document interprets each standard with added discussion points clarifying the criteria necessary for compliance. The most recent version of this Guidance Document should also be used during the audit and documented on the cover of the Audit Document(s).</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 15.5 | Database Standard 15.5 |
|---|------------------------|
| <p>The completed Audit Document(s) should be prepared by the auditor(s) and sent to the laboratory within 30 days of the audit. The Audit Document includes the completed checklist and associated appendices with any areas of noncompliance listed under the Findings section of Appendix A. All findings must be clearly identified and referenced to the appropriate Standard. Recommendations must not be included in the Audit Document.</p> | |
| <p>The laboratory must ensure that an adequate response detailing any incorporated corrective action, if appropriate, has been generated with regard to all findings and documented within the Response section of Appendix A. A laboratory's written course of action or response to the findings should be maintained as part of the audit documentation.</p> | |
| <p>Prior audit documentation must be available to the auditor(s) as a measure of the laboratory's response to previous findings. It is critical that findings identified in a previous audit document be thoroughly addressed and resolved (if possible) within the DNA laboratory's capabilities. To fulfill the requirements associated with Standard 15.5, the laboratory must show evidence of a response and/or corrective action to all findings detailed during the previous audit.</p> | |

Standard 5.3.4.4 requires the CODIS administrator to ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures; therefore, internal and external audit documentation and, if applicable, corrective action must be provided to the CODIS administrator as required by **Standard 15.5.1**.

To comply with **Standard 15.5.2**, it is incumbent on the NDIS participating laboratory to document for each external audit, the date that the Audit Document was received from the auditor(s) and the date that the laboratory sent the external audit documentation and laboratory responses to the FBI. The laboratory response may include a notification to the NDIS Custodian if the laboratory needed to request an extension of time for sending the required audit documentation.

For non-NDIS participating laboratories, **Standards 15.5.1** and **15.5.2** are not applicable.

Latest Revision: 07/01/2020

| Forensic Standard 15.6 | Database Standard 15.6 |
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Prior audit documentation must be available to the auditor(s). Appendices may be requested to ensure education, experience and training of personnel and validations have been previously memorialized.

Latest Revision: 07/01/2020

Standard 16. Professional Development

| Forensic Standard 16.1 | Database Standard 16.1 |
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Continuing education is intended to maintain technical qualifications through participation in activities that expand an individual's knowledge and awareness of topics relevant to the field of DNA analysis.

Activities in the laboratory's training program that are required for establishing an individual's competency are not considered continuing education with respect to this standard.

Latest Revision: 07/01/2020

| Forensic Standard 16.1.1 | Database Standard 16.1.1 |
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Laboratory management must provide the technical leader, CODIS administrator(s), analyst(s), and technical reviewer(s) with the opportunity to stay abreast of developments and issues in the field of forensic or databasing DNA analysis annually. Continuing education in topics relevant to the field of forensic or databasing DNA analysis may include seminars on new methods and techniques for obtaining DNA profiles, lectures on troubleshooting current methods or techniques, courses on providing testimony on DNA results and conclusions, as well as the QAS auditor training or relevant CODIS training.

A technical leader or CODIS administrator who is newly hired/appointed or an analyst or technical reviewer who completes the laboratory's initial training program within the calendar year is not expected to complete the 8 hours of continuing education until the next calendar year.

Although continuing education should be formalized (e.g., lectures, seminars, professional meetings), this does not necessarily require earned credit hours or grade evaluations; however, this would be acceptable.

Reading of scientific literature and subsequent lab-sponsored discussions (e.g., journal club, article presentation) do not count toward the continuing education hours. Activities required as part of the laboratory's training program and/or that are required for establishing an individual's competency do not count toward the continuing education hours.

Regional, national, or international conferences related to forensic or biological sciences that include presentations relevant to forensic or databasing DNA typically provide sufficient content to satisfy the continuing education requirement. The program agenda, record of presentations, or curriculum vitae of presenters is not required for regional, national, or international conferences.

The technical leader must approve the use of multimedia or internet delivered programs to satisfy continuing education hours. The approval of multimedia or internet delivered continuing education, to include the QAS auditor training or relevant CODIS training, may be documented for the specific course or may be documented for each individual completing a course. Completion must be documented and documentation must include the time required to complete the program. For multimedia training that is internally generated (e.g., video recording of an internal lecture), technical leader approval and the time needed to complete the training may be documented prior to or with the dissemination of such training.

Latest Revision: 07/01/2020

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| Forensic Standard 16.1.2 | Database Standard 16.1.2 |
| The laboratory program must include how completion of ongoing reading of the literature will be documented. | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 16.2 | Database Standard 16.2 |
| Individuals who provide testimony as part of their current positions must be monitored at least once annually. The laboratory's program must include how to document analysts who do not testify during the calendar year (e.g., list of analyst(s) that did not testify). | |

The elements that may be evaluated by the laboratory should include the analyst's ability to communicate clearly and accurately within the bounds of the scientific expertise.

The mechanisms for testimony review should include how a review may be conducted.

If necessary, corrective actions related to testimony monitoring shall be handled in accordance with **Standard 14**.

Latest Revision: 07/01/2020

Standard 17. Outsourcing Ownership

| Forensic Standard 17 | Database Standard 17 |
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| <p>As defined in Standard 2, ownership applies if any of the following will occur:</p> <ol style="list-style-type: none"><li data-bbox="261 835 1382 940">1. The NDIS participating laboratory will use any samples, extracts, or materials from the vendor laboratory for the purposes of forensic testing (e.g., a vendor laboratory prepares an extract that will be analyzed by the NDIS laboratory);<li data-bbox="261 982 1317 1054">2. The NDIS participating laboratory will interpret the data generated by the vendor laboratory;<li data-bbox="261 1096 1333 1201">3. The NDIS participating laboratory will issue a report describing or drawing conclusions on the results of the DNA analysis performed by the vendor laboratory; or<li data-bbox="261 1243 1382 1314">4. The NDIS participating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory. <p>Laboratories shall demonstrate compliance with Standard 17 if any of the criteria of ownership are or may become applicable, including situations where a vendor laboratory subcontracts. Except as provided in Standard 17.2.2, failure to comply with Standard 17 by an NDIS participating laboratory or non-NDIS participating laboratory will preclude the entry, searching or uploading of the outsourced DNA data into CODIS.</p> <p>A profile generated by another NDIS participating laboratory from a casework reference sample that the NDIS participating laboratory will only use for comparison is not considered ownership. A profile generated from a casework reference sample by another NDIS participating laboratory may be used by an NDIS participating laboratory to issue a report describing or drawing conclusions on the results of DNA analysis performed in the NDIS participating laboratory (or to results of the DNA analysis performed by a vendor laboratory when in compliance with Standard 17)</p> | |

provided that the report does not describe the results of the casework reference sample (i.e., single source male profile). The laboratory should ensure it is clear that the results from casework reference sample used for comparison were generated by another laboratory.

Compliance with **Standard 17** is not applicable if the NDIS participating laboratory has not outsourced any DNA-related services for the purposes of taking ownership in the scope of the audit. However, if a contract for outsourcing is in place or outsourcing is occurring without a contractual agreement, the laboratory must demonstrate compliance with the applicable portions of **Standard 17** (e.g., vendor laboratory accreditation, technical specification approvals, site visits, and ownership review procedures) even if no samples were outsourced in the scope of the audit.

Compliance with **Standard 17** is not applicable and ownership does not apply to the reporting of missing person associations between NDIS participating laboratories within CODIS. Generally, the NDIS participating laboratory that processed the Unidentified Human Remains (UHR) issues a report of association, including applicable statistics, that clearly references all laboratories involved in the association. Datalinking that occurs between two NDIS participating laboratories does not constitute ownership. DNA data is not included in this report of association.

For vendor laboratories, the following standards are not applicable: Standards 17.1.1, 17.2, and Standards 17.2.2, 17.3 and 17.4 and their substandards.

Latest Revision: 07/01/2020

| Forensic Standards 17.1 | Database Standards 17.1 |
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| <p>For Standard 17.1, a vendor laboratory must comply with the current FBI <i>Quality Assurance Standards for Forensic DNA Testing Laboratories</i> or <i>DNA Databasing Laboratories</i> in their entirety, as applicable, and the accreditation requirements of federal law.</p> | |
| <p>For Standard 17.1.1, an NDIS participating laboratory that has entered into an outsourcing agreement, or if criteria of ownership applies, shall maintain the vendor laboratory's external audit documentation to include the audit document and the vendor laboratory's responses and/or corrective actions for any findings. Such documentation or copies must be reviewed by the NDIS participating laboratory's technical leader and be retained by the NDIS participating laboratory. Laboratories that use FBI coordinated visits do not have to retain a vendor laboratory's accreditation and external audit documentation separately.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| | Database Standard 17.1.2 |
|------------------------------------|--------------------------|
| <p>No additional guidance</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standards 17.2 and 17.2.1 | Database Standards 17.2 and 17.2.1 |
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| <p>Standard 17.2 applies to those laboratories that have entered into an outsourcing agreement or have had a multi-year agreement in effect with a vendor laboratory since their last external audit.</p> <p>For Standard 17.2, the NDIS participating laboratory must maintain the date of the technical leader's documented approval of the technical specifications of the outsourcing agreement as required in Standard 17.2 and/or the documented prior approval of the acceptance of ownership of the DNA data as specified in Standard 17.2.1.</p> <p>For Standard 17.2.1, when a vendor laboratory is performing forensic DNA analysis for a law enforcement agency or entity other than the NDIS participating laboratory, it is incumbent on the vendor laboratory to obtain approval from the technical leader of the NDIS participating laboratory that has agreed to accept ownership of the DNA data, as well as the date that the vendor laboratory first initiated analysis for a specific case or set of cases. The approval provided by the NDIS participating laboratory's technical leader to the vendor laboratory must precede the vendor laboratory initiating analysis. Approval could be in the form of an e-mail but must be provided in writing. If the vendor laboratory has not performed work on any samples intended for the purposes of ownership by an NDIS participating laboratory that would require the prior approval by the NDIS participating laboratory, this standard is not applicable.</p> <p>For the NDIS participating laboratory, Standard 17.2.1 is not applicable; however, if compliance with Standard 17.2 and/or 17.2.1 have not been demonstrated and ownership applies, the NDIS participating laboratory must demonstrate compliance with Standard 17.2.2.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

| Forensic Standard 17.2.2 | |
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| <p>If, in rare instances, the vendor laboratory fails to obtain prior approval from the technical leader of the NDIS participating laboratory which will take ownership, the NDIS participating laboratory can accept the results of analysis if the conditions described in Forensic Standard 17.2.2 are met.</p> <p>For Forensic Standard 17.2.2.2, the NDIS participating laboratory's technical leader must approve the technical specifications of the testing conducted.</p> <p>For Forensic Standard 17.2.2.3, the NDIS participating laboratory's technical leader must perform an on-site visit or review and document acceptance of an on-site visit of the vendor laboratory that was performed within 18 months, prior to or following, initiation of the conducted analysis. The on-site visit must be documented in accordance with Standard 17.4.</p> | |
| <p>Latest Revision: 07/01/2020</p> | |

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| | Database Standard 17.2.2 |
| <p>For Database Standard 17.2.2, documentation will need to be retained by the NDIS participating laboratory demonstrating compliance with Database Standard 17.2 and/or 17.2.1 as well as the date that the NDIS participating laboratory first uploaded DNA data or first accepted DNA data for upload to CODIS. Approval could be in the form of an e-mail but must be provided in writing. This standard also applies to data generated by a vendor laboratory when there is no existing outsourcing agreement, which includes contractual agreements, between the vendor and the laboratory accepting the data. If the NDIS participating laboratory has not uploaded or accepted DNA data for upload into CODIS from a vendor laboratory, this standard is not applicable.</p> | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standard 17.3 | Database Standard 17.3 |
| <p>To satisfy the requirements of Standard 17.3, the laboratory must have procedures for verifying the integrity of data received from a vendor laboratory of which the NDIS participating laboratory will take ownership of and must demonstrate compliance (as applicable) with each of the substandards of Standard 17.3.</p> | |
| Latest Revision: 07/01/2020 | |

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| | Database Standard 17.3.1 |
| No additional guidance | |
| Latest Revision: 07/01/2020 | |

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| Forensic Standards 17.3.1 – 17.3.2 | Database Standards 17.3.2 – 17.3.3 |
| <p>The reviews required by Forensic Standards 17.3.1 and 17.3.2/Database Standards 17.3.2 and 17.3.3 may be performed by an employee or contract employee of the NDIS participating laboratory.</p> <p>In the event that an NDIS participating laboratory chooses to conduct a search of outsourced DNA data in SDIS prior to the completion of the ownership review, the NDIS participating laboratory must, at a minimum, verify the CODIS eligibility and the correct specimen category for entry into CODIS. Since the outsourced DNA data will have been technically reviewed by the vendor laboratory in accordance with Standard 12, the search of outsourced DNA data at SDIS may be done prior to the completion of the ownership review.</p> <p>Forensic Standard 17.3.1/Database Standard 17.3.2 is not applicable to requests for the searching of DNA data for investigative purposes between NDIS laboratories that do not involve outsourcing agreements.</p> <p>For Forensic Standard 17.3.2/Database Standard 17.3.3, the ownership review of a vendor laboratory’s data shall be performed by an analyst or technical reviewer who is qualified by the NDIS participating laboratory in the technology, platform, and typing</p> | |

test kit used to generate the data. This ownership reviewer must participate in an NDIS participating laboratory's external proficiency testing program (or be authorized to review a legacy technology, typing test kit, and/or platform according to **Forensic Standard 6.8**) to the extent necessary to be proficient in the technology, platform, and typing test kit under review in the outsourced data. For example, an analyst or technical reviewer participates and is proficiency tested on casework using one typing test kit, technology, or platform and performs the ownership review of outsourced casework which was analyzed using a different technology, platform and/or typing test kit. Such analyst or technical reviewer must also be proficiency tested on at least the ownership review of the technology, platform and/or typing test kit used by the outsourcing laboratory. The NDIS laboratory must also maintain the proficiency test records and qualifications of any contract employee that performs ownership reviews. If proficiency testing for a contract technical reviewer is administered by another NDIS participating laboratory refer to the guidance under **Standard 13.1.5.3**.

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Forensic Standards 17.3.3 – 17.3.4

Database Standards 17.3.4 – 17.3.5

The ownership reviews must include the elements listed under **Forensic Standards 17.3.3** and **17.3.4/Database Standards 17.3.4** and **17.3.5**, as applicable.

Forensic Standard 17.3.3.3 is not applicable if the NDIS participating laboratory does not receive a final report from the vendor laboratory in accordance with their outsourcing agreement.

As provided in **Database Standard 17.3.3**, a portion of the ownership review may be accomplished through the use of an NDIS approved and internally validated Expert System.

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Forensic Standard 17.4

Database Standard 17.4

To satisfy the requirements of **Standard 17.4**, the laboratory must have and follow procedures and demonstrate compliance (as applicable) with each of the substandards of **Standard 17.4**.

For **Standard 17.4**, except as provided in **Forensic Standard 17.2.2.3**, an on-site visit must be performed prior to the vendor laboratory's initiating work on a forensic or on a database, known, or casework reference sample, whether performed as a part of a contractual agreement or as a part of an agreement of the NDIS participating laboratory to accept ownership of data outside of an existing contractual agreement, regardless of the number of samples or cases being accepted.

The laboratory shall retain documentation demonstrating the date the on-site visit was performed, a summary of the visit, and the documentation of the personnel who performed the on-site visit. While an on-site visit is not required if an individual is only providing technical review services for the NDIS participating laboratory, the NDIS

participating laboratory's technical leader shall evaluate how and where such services are being performed and document their approval to ensure compliance with **Standard 11.3**. For example, if the technical reviewer will not be performing the technical review services at the NDIS participating laboratory, the technical leader will want to know where the services will be performed and the security precautions in place to safeguard the confidentiality of the information being reviewed. The technical leader will want to ensure that only authorized persons have access to the information being reviewed if such information is taken outside the controlled NDIS participating laboratory environment.

Standard 17.4.2 is applicable when an outsourcing agreement has been extended (e.g., extensions, renewals or re-award) and the technical specifications (e.g., technology, platform and typing amplification test kit) used to generate the DNA data have not changed. If an outsourcing agreement was in force with the specific vendor laboratory in an essentially consistent, continuous manner (with a delay not to exceed six months), it is not required that an additional, initial on-site visit be performed, as required for new outsourcing agreements in **Standard 17.4.1**.

It is noted that an on-site visit is different from an external audit and does not necessarily require that an external audit be performed during an on-site visit.

The technical leader of the NDIS participating laboratory may elect to accept documentation generated from an on-site visit of the vendor laboratory conducted by an NDIS participating laboratory using the same technology, platform, and typing test kit. Alternatively, the technical leader of the NDIS participating laboratory may accept an on-site visit coordinated by a designated FBI employee. For **Standard 17.4.1.1** and/or **17.4.2.1**, an NDIS participating laboratory accepting an on-site visit from another NDIS participating laboratory or the FBI shall have documentation demonstrating the review and approval of the on-site visit by the NDIS participating laboratory's technical leader. The on-site visit documentation should include the date the on-site visit was performed, a summary of the visit, and the personnel who performed the on-site visit.

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Appendices

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| Appendix A - Findings and Responses | |
| Refer to Standard 15.5 | |
| | Latest Revision: 07/01/2020 |
| Appendix B - Contingency Plan Notification Form | |
| Refer to Standard 4.1.6 | |
| | Latest Revision: 07/01/2020 |
| Appendix C - Auditor Self-Certification | |
| Refer to Standards 15.2 and 15.3 | |
| | Latest Revision: 07/01/2020 |
| Appendix D - Personnel | |
| Refer to Standard 5 and Standard 15.2.1 | |
| | Latest Revision: 07/01/2020 |
| Appendix E - Approved Validations | |
| Refer to Standard 8 and Standard 15.2.2 | |
| | Latest Revision: 07/01/2020 |